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NELLCOR

OxiMax®
N-560™

Pulse Oximeter
Operator's Manual

This ISM device complies with Canadian ICES-001.

Cet appareil ISM est conforme à la norme NMB-001 Canada.

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Warnings

Warnings are identified by the WARNING symbol shown above.

Warnings alert the user to potential serious outcomes (death, injury, or adverse events) to the patient or user.

WARNING: Explosion hazard. Do not use the N-560™ pulse oximeter in the presence of flammable anesthetics or gases.

WARNING: Pulse oximetry readings and pulse signals can be affected by certain ambient environmental conditions, sensor application errors, and certain patient conditions. See the appropriate sections of the manual for specific safety information.

WARNING: Ensure that the speaker is clear of any obstruction. Failure to do so could result in an inaudible alarm tone.

Cautions

Cautions are identified by the CAUTION symbol shown above.

Cautions alert the user to exercise care necessary for the safe and effective use of the N-560.

CAUTION: When connecting the N-560 to any instrument, verify proper operation before clinical use. Both the N-560 and the instrument connected to it must be connected to a grounded outlet. Accessory equipment connected to the N-560's data interface must be certified according to IEC Standard 60950 for data-processing equipment or IEC Standard 60601-1 for electromedical equipment. All combinations of equipment must be in compliance with IEC Standard 60601-1-1 systems requirements. Anyone who connects additional equipment to the signal input port or signal output port (N-560 data port connector) configures a medical system and is therefore responsible for ensuring that the system complies with the requirements of system standard IEC Standard 60601-1-1 and the electromagnetic compatibility system standard IEC Standard 60601-1-2. The N-560 accuracy may degrade if it is connected to secondary I/O devices when the instrument is not connected to earth reference.

CAUTION: Do not lift the N-560 by the sensor cable or power cord because the cable or cord could disconnect from the N-560, causing damage to the N-560 or injuring the patient.

CAUTION: Federal law (U.S.A.) restricts this device to sale by or on the order of a physician.

Notes

Notes are identified by the Note symbol shown above.

Notes provide additional useful information.

Note: Sensor LED light emissions fall within Class 1 level, according to IEC 60825-1:2001. No special safety precautions are required.

Introduction

WARNING: The N-560 is intended only as an adjunct in patient assessment. It must be used in conjunction with clinical signs and symptoms. Do not make any clinical judgments based on the oximeter's measurements only.

Intended Use for the N-560

The N-560 Pulse Oximeter is indicated for the continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate. The N-560 is intended for use with neonatal, pediatric, and adult patients who are well or poorly perfused, in hospitals, hospital-type facilities, intra-hospital transport, and home environments. For prescription use only.

Note: Hospital use typically covers such areas as general care floors, operating rooms, special procedure areas, intensive and critical care areas, within the hospital plus hospital-type facilities. Hospital-type facilities include physician office-based facilities, sleep labs, skilled nursing facilities, surgicenters, and sub-acute centers.

Intra-hospital transport includes transport of a patient within the hospital or hospital-type facility.

Use with any particular patient requires the selection of an appropriate oxygen transducer (sensor) as described in this Operator's Manual.

How to Use this Manual

All users should read this manual thoroughly. More experienced users of the N-560 can directly go to topics for the information they require. This manual is available on the internet at:

http://www.mallinckrodt.com/respiratory/resp/Serv_Supp/ProductManuals.html

Description of Controls, Indicators, and Symbols

Identification of Front Panel Buttons and Symbols

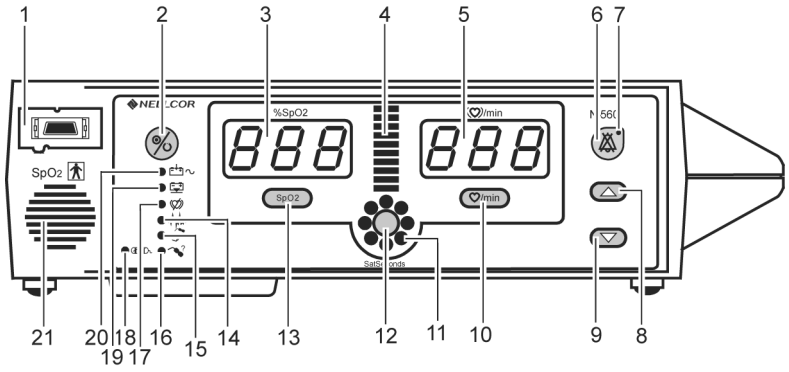
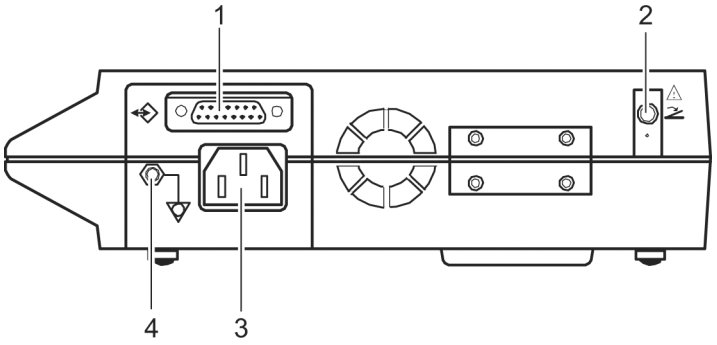


Figure 1: Front Panel Buttons and Symbols

1. SpO2 Sensor Port	12. **SatSeconds Alarm Limit** Button
2. **Power On/Off** Button	13. **SpO2 Alarm Limit** Button
3. %SpO**2** Display	14. **Interference** Indicator
4. **Pulse Amplitude** Indicator	15. **Sensor Off** Indicator
5. **Pulse Rate** Display	16. **Sensor Message** Indicator
6. **Alarm Silence** Button	17. **Pulse Search** Indicator
7. **Alarm Silence** Indicator	18. **Data In Sensor** Indicator
8. **Adjust Up** Button	19. **Low Battery** Indicator
9. **Adjust Down** Button	20. **AC Power** Indicator
10. **Pulse Rate Alarm Limit** Button	21. Speaker
11. *SatSeconds*™ Display	

Identification of Rear Panel Components

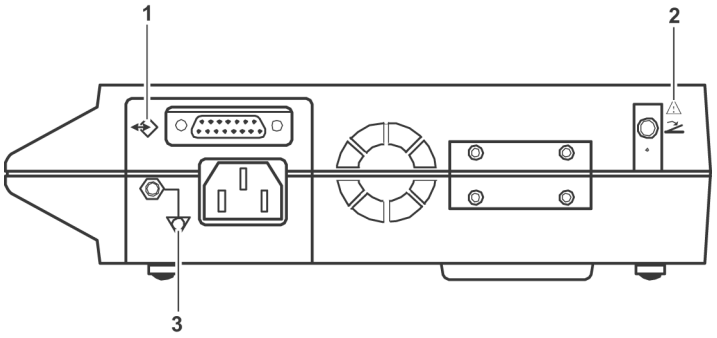


1. Data Port Connector	3. AC Power Connector
2. Visual Alarm Connector	4. Equipotential Connector (ground)

Figure 2: Rear Panel Symbols

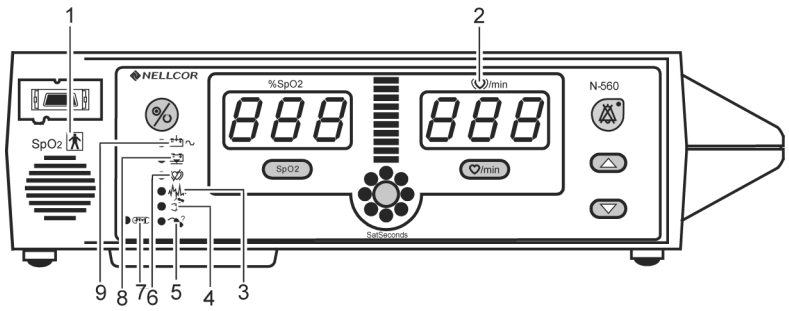
N-560 Symbols

The symbols that are located on the rear panel of the N-560 are as follows:



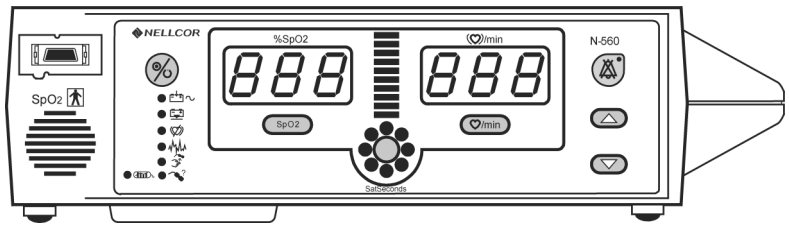
1. Data Interface	3. Equipotential Terminal (ground)
2. Caution - Do not connect while power is on	

The symbols that are located on the front panel of the N-560 are as follows:



1. Type BF Applied Part - Not Defibrillator Proof	6. Pulse Search
2. Pulse Rate	7. Data In Sensor
3. Interference	8. Low Battery
4. Sensor Off	9. AC Power/Battery Charge
5. Sensor Message	

Description of Controls



Note: Each button press, except the **Power On/Off** button, should result in either a valid or an invalid button tone. If the button pressed fails to emit a tone, contact qualified service personnel.

The **Power On/Off** button is used to turn the N-560 on or off.

The **Alarm Silence** button is used to silence current alarms for the alarm silence duration period. When an alarm has been silenced, pressing the button again reactivates, or “unsilences” the alarm. It is also used to view and adjust alarm silence duration and alarm volume.

The **Adjust Up** button is used to increase alarm limit values, alarm silence duration, pulse beep volume, alarm volume, and data port baud rate. The **Adjust Up** button is used to select the communication protocol and time settings. Press the **Adjust Up** button one time to increase the display by one digit. Holding the **Adjust Up** button down for more than one second cause the display digits to scroll.

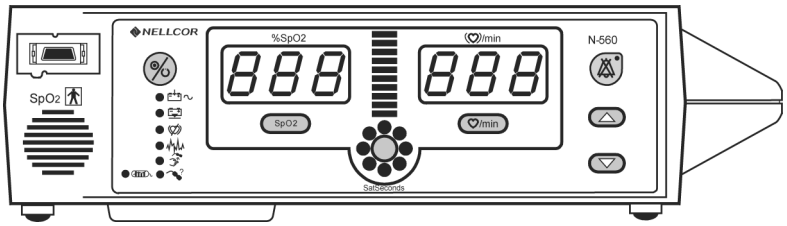
The **Adjust Down** button is used to decrease alarm limit values, alarm silence duration, pulse beep volume, alarm volume, and data port baud rate. The **Adjust Down** button is used to select the communication protocol and time settings. Press the **Adjust Down** button one time to decrease the display by one digit. Holding the **Adjust Down** button down for more than one second cause the display digits to scroll.

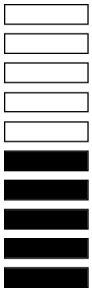
The **SpO2 Alarm Limit** button is used to view the SpO_2 alarm limit. When the **SpO2 Alarm Limit** button is pressed at the same time as the **Pulse Rate Alarm Limit** button for approximately three seconds, the menu options are enabled.

The **Pulse Rate Alarm Limit** button is used to view the pulse rate alarm limit. When the **Pulse Rate Alarm Limit** button is pressed at the same time as the **SpO2 Alarm Limit** button for approximately three seconds, the menu options are enabled.

The **SatSeconds Alarm Limit** button is used to view the *SatSeconds* alarm limit. When pressed, the *SatSeconds* limit options are enabled. The **Adjust Up** and **Adjust Down** buttons are used to change the *SatSeconds* limit settings.

Description of Displays and Indicators





The **Pulse Amplitude** Indicator (blip bar). A 10-segment LED that indicates pulse beat and shows the relative (non-normalized) pulse amplitude. As the detected pulse becomes stronger, more bars light with each pulse.

%SpO2 The %SpO2 Display. Shows the saturation level of oxygenated hemoglobin. The display value flashes zero during loss-of-pulse alarms and flashes the SpO2 value in red when the SpO2 is outside the alarm limits. During pulse search, the N-560 continues to update the display. If alarm limits have been changed from their power-on defaults, a decimal point (.) is displayed after the SpO2 value (100.).

/min The **Pulse Rate** Display. Shows the pulse rate in beats per minute. It flashes zeros during loss-of-pulse alarms and flashes the beats per minute value in red when the pulse rate is outside of the alarm limit. During pulse search, the N-560 continues to update the display. Pulse rates outside of the pulse rate range (20 to 250 bpm) are displayed as the closest value within the range. If alarm limits have been changed from their power-on defaults, a decimal point (.) is displayed after the pulse rate value (112.).

The **AC Power** Indicator. Lights continuously when the N-560 is connected to AC power. It also indicates that the battery is charging. It is off when the N-560 is being powered by its internal battery.

The **Low Battery** Indicator. Lights continuously to indicate that 15 or fewer minutes of battery capacity remain. The **Low Battery** indicator flashes when the battery is critically low.

The **Alarm Silence** Indicator. Lights continuously when an audible alarm has been silenced. It flashes when the alarm silence duration has been set to OFF.

The **Interference** Indicator. Lights whenever the *OxiMax* software detects that the incoming signal quality is degraded due to interference (see *Interference Explained* on page 11).

An intermittently lit **Interference** indicator is common during patient monitoring, and indicates that the *OxiMax* algorithm is dynamically adjusting the amount of data required for measuring SpO_2 and Pulse Rate. When lit continuously, it indicates that the *OxiMax* algorithm has extended the amount of data required for measuring SpO_2 and Pulse Rate, and, consequently, fidelity in tracking rapid changes in these values may be reduced (see *Description of Displays and Indicators* on page 9).

The **Pulse Search** Indicator. Lights continuously prior to initial acquisition of a pulse signal and during prolonged and challenging monitoring conditions. It flashes during a loss-of-pulse signal.

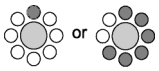
The **Sensor Off** Indicator is lit when either the sensor is invalid, or no longer on the patient's finger. It usually indicates that the sensor is not on the patient.

The **Sensor Message** Indicator. Lights when the N-560 cannot determine an SpO2 level or a pulse rate. The sensor message recommendations for improving the signal are:

- Reposition sensor
- Check or change adhesive wrap
- Choose alternate site
- Warm site
- Cover sensor
- Use forehead, nasal, or ear sensor (adult patients only)
- Use *OxiMax* adhesive sensor
- Secure cable
- Secure with headband (*Max-Fast*)
- Remove nail polish

- Loosen sensor (too tight)
- Isolate external interference (electrosurgical device, cell phone)
- Clean site (MAX-R)

The **Data In Sensor** Indicator. The indicator blinks for approximately one minute when initially connected to the N-560 to indicate that the attached *OxiMax* sensor contains a patient sensor event record. The indicator lights continuously to indicate that the attached sensor memory is full. The indicator does not light when there is no data in the sensor, even though a valid sensor is connected to the N-560.



The *SatSeconds*™ Indicator. Fills in clockwise as the *SatSeconds* alarm management approaches the *SatSeconds* alarm limit threshold. All segments of the *SatSeconds* indicator flash during a *SatSeconds* alarm. When a *SatSeconds* setting other than OFF is selected, the green LED at the top of the *SatSeconds* indicator will light. The green LED at the 12-o'clock position indicates that *SatSeconds* alarm management is engaged.

Interference Explained

Interference is a term that was formally introduced in ISO9919:2005, “Medical electrical equipment — Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use”. Interference may arise from a number of sources, alone or in combination, and the term refers to the effects on the incoming red and IR signals caused by physiological conditions, medical procedures, or external agents. The effect of interference on a pulse oximeter is due only to the amount of interference, and is generally nondiscriminatory as to its source. Interference may or may not affect the accuracy of measurements, depending upon its severity, nature, or duration.

Factors which may result in interference include but are not limited to:

- incorrect sensor application
  - sensor placement on an extremity with a blood pressure cuff, arterial catheter, or intravascular line
  - sensor applied too tightly
  - incorrect sensor for placement site
- intravascular dyes, such as indocyanine green or methylene blue
- externally applied coloring agents, such as nail polish, dye, or pigmented cream
- failure to cover the sensor with opaque material in high ambient light conditions, for example, conditions created from one or more of the following sources:
  - surgical lights, especially xenon light sources
  - bilirubin lamps
  - fluorescent lights
  - infrared heating lamps
  - direct sunlight
- physical movement, either patient or imposed activity
- venous pulsation
- dysfunctional hemoglobin
- low perfusion
- intermittent pulsatility or arrhythmia
- electromagnetic interference (EMI)
- ventilator-induced pressure changes

Description of Audible Indicators

Following are descriptions of N-560 audible indicators.

Power-On Self-Test Pass	A 1-second tone indicating that the N-560 has been turned on and has successfully completed the power-on self-test
Valid Button Press	A short, medium-pitched tone indicating that an appropriate button has been pressed
Invalid Button Press	A short, low-pitched tone indicating that a button has been pressed that is not appropriate for the current state of the N-560
High Priority Alarm	A high-pitched, fast-pulsating tone indicating loss of pulse
Medium Priority Alarm	A medium-pitched, normal-pulsating tone indicating an SpO_2 or pulse rate limit violation
Low Priority Alarm	A low-pitched, slow-pulsating tone indicating a sensor disconnect, low battery, or N-560 failure
Alarm Silence Reminder	Three beeps that sound approximately every 3 minutes when alarms are silenced with the alarm silence duration set to OFF
Pulse Beep	A single beep sounds for each detected pulse. The pitch changes as monitored SpO_2 values increase or decrease.
Volume Setting Tone	A continuous tone that is used to adjust the alarm volume
Confirmation Tone	Three beeps sound to indicate that default settings have been saved or reset to factory defaults or trend data has been deleted

Setting up the N-560

WARNING: Explosion hazard. Do not use the N-560 pulse oximeter in the presence of flammable anesthetics or gases.

WARNING: Pulse oximetry readings and pulse signals can be affected by certain ambient environmental conditions, sensor application errors, and certain patient conditions. See the appropriate sections of the manual for specific safety information.

WARNING: To ensure patient safety, do not place the N-560 in any position that might cause it to fall on the patient.

WARNING: As with all medical equipment, carefully route patient cabling to reduce the possibility of patient entanglement or strangulation.

WARNING: Disconnect the N-560 and Nellcor sensor from the patient during magnetic resonance imaging (MRI) scanning. Induced current could potentially cause burns. The N-560 may affect the MRI image; the MRI unit may affect the accuracy of oximeter measurements.

WARNING: To ensure accurate performance and prevent device failure, do not subject the N-560 to extreme moisture, such as direct exposure to rain. Such exposure may cause inaccurate performance or device failure.

WARNING: Do not use an N-560, sensor, cables, or connectors that appear to be damaged.

WARNING: The N-560 is not defibrillator-proof. However, it may remain attached to the patient during defibrillation or while an electrosurgical unit is in use, but the readings may be inaccurate during use and shortly thereafter.

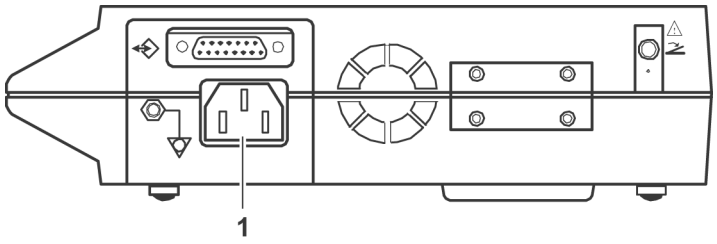
WARNING: In the USA, do not connect the N-560 to an electrical outlet controlled by a wall switch because the N-560 may be accidentally turned off.

WARNING: Use only the DOC-10 pulse oximetry cable with the N-560. Use of another sensor cable will have an adverse effect on performance. Do not attach any cable that is intended for computer use to the sensor port. Do not connect any device other than a Nellcor-approved sensor to the sensor connector.

List of Components

- N-560 Pulse Oximeter
- *Nellcor* Sensor or Assortment Pack
- DOC-10 Pulse Oximeter Cable
- N-560 Operator's Manual
- Hospital-Grade Power Cord or power cord appropriate for country of sale
- Sensor Accuracy Grid
- Quick Guide

Connecting the N-560 to AC Power



1. Power Connector

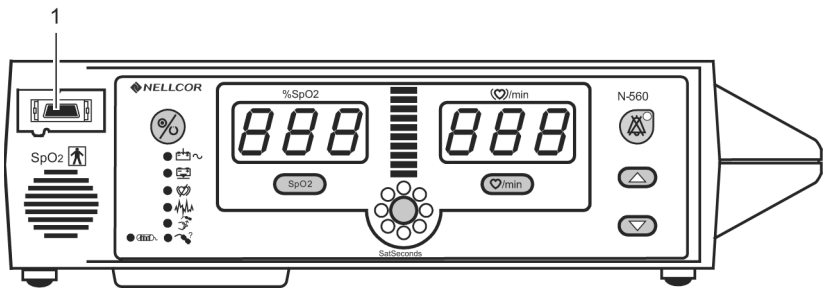
1. Plug the female connector of the power cord into the N-560 AC power connector (1).

2. Plug the male connector of the power cord into a properly grounded AC outlet.

3. Verify that the **AC Power** Indicator is lit.

Connecting a Sensor to the N-560

WARNING: Use only the DOC-10 pulse oximetry cable with the N-560. Use of another sensor cable will have an adverse effect on performance. Do not attach any cable that is intended for computer use to the sensor port. Do not connect any device other than a Nellcor-approved sensor to the sensor connector.



1. SpO2 Sensor Port

1. Connect a DOC-10 pulse oximetry cable to the SpO2 Sensor Port (1) on the front of the N-560.

2. Connect an SpO2 Sensor to the other end of the DOC-10 pulse oximetry cable. Plug the sensor connector firmly into the DOC-10 pulse oximetry cable.

Battery Operation

WARNING: Dispose of an old battery by following local guidelines for disposal of nickel metal hydride batteries.

Operating the N-560 on Battery Power

The N-560 has an internal battery that may be used to power the N-560 during transport or when AC power is not available. A new, fully charged battery will provide at least 8 hours of monitoring time under the following conditions: no audible alarms sound and no serial output devices are attached.

Note: Whenever the N-560 is connected to AC power, the battery is being charged. Therefore, it is recommended that the N-560 remain connected to AC power when not in use. This will make a fully charged battery available for use at any time.

The N-560 cannot operate with a dead battery. Before attempting to turn on an N-560 with a depleted battery, first plug the N-560 into an AC outlet. The N-560 may then be powered on.

To charge a low or dead battery, connect the N-560 to AC power. A full charge of a dead battery takes 6 hours.

When all of the following conditions are present for 15 minutes, the N-560 will automatically shut down:

- N-560 is running on battery power
- No buttons have been pressed
- No pulse has been detected (for example, when no patient is connected to the sensor or the sensor is disconnected)
- No alarms are present (other than low battery or a non-correctable error)

Low Battery Indicator

The **Low Battery** Indicator lights and a low priority alarm begins to sound when 15 minutes but not more than 20 minutes of monitoring time remain on the existing battery charge. This alarm cannot be silenced while running on battery power. Connecting the N-560 to AC power will silence the alarm. If the N-560 is not connected to AC power within approximately 15 minutes, the N-560 will shut off.

Note: As the battery is used and recharged over a period of time, the amount of time between the onset of the low battery alarm and the N-560 shutoff may become shorter.

It is recommended that qualified service personnel replace the internal battery every 24 months.

CAUTION: If the N-560 is to be stored for 3 months or longer, notify service personnel to remove the battery from the N-560 prior to storage. Recharge the battery when it has not been charged for 3 or more months.

The **Low Battery** Indicator flashes and a high priority alarm begins to sound when the battery reaches the lowest battery voltage at which an N-560 can support normal operation. This alarm cannot be silenced while running on battery power. If the N-560 is not connected to AC power, the N-560 will shut off after 10 seconds.

Using the N-560

Turning on the N-560

Discussion

Before using the N-560 in a clinical setting, you must verify that the N-560 is working properly and is safe to use. Proper working condition can be verified by successful completion of the Power-On Self-Test (POST), described in the following section.

WARNING: The N-560 should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the N-560 should be observed to verify normal operation in the configuration in which it is used.

CAUTION: If any indicator or display element does not light, or the speaker does not sound, do not use the N-560. Instead, contact qualified service personnel, your local Nellcor representative, or Nellcor's Technical Services Department, 1.800.635.5267.

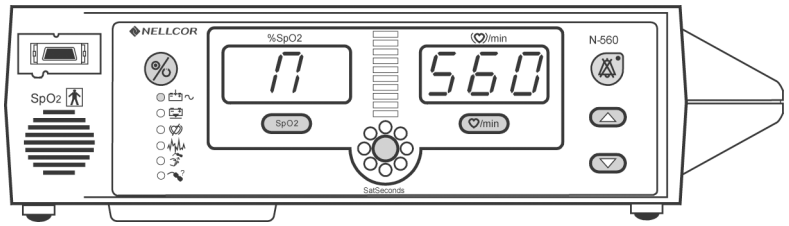
Note: The N-560 should complete the POST function within 12 seconds.

Procedure

1. Turn on the N-560 by pressing and holding the **Power On/Off** button for more than one second.

2. The N-560 displays/sounds:

Display	Sound
5 (in pulse rate left window)	one beep tone
6 (in pulse rate center window)	one beep tone
0 (in pulse rate right window)	one beep tone
n (in SpO2 left window)	none
n (in SpO2 center window)	none

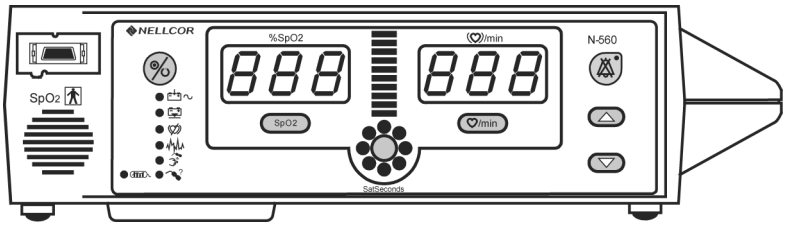


3. The N-560 automatically starts the Power-On Self-Test (POST), which tests N-560 circuitry and functions.

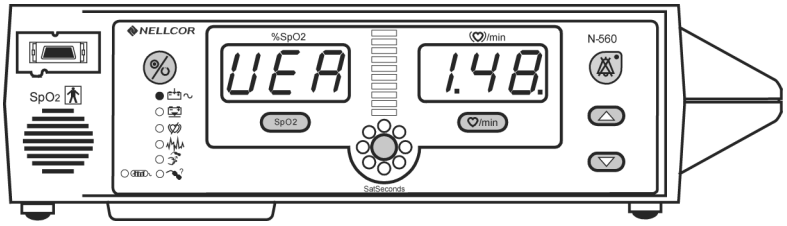
CAUTION: During POST (immediately after power-up), confirm that all display segments and indicators light, and the speaker sounds a 1-second pass tone.

4. While performing POST, the self-test display appears for approximately 2 to 4 seconds. During this time:

- All indicators illuminate
- All segments of all numeric digits light and change from red to green
- All segments of the **Pulse Amplitude** Display light
- All segments of the *SatSeconds* indicator light



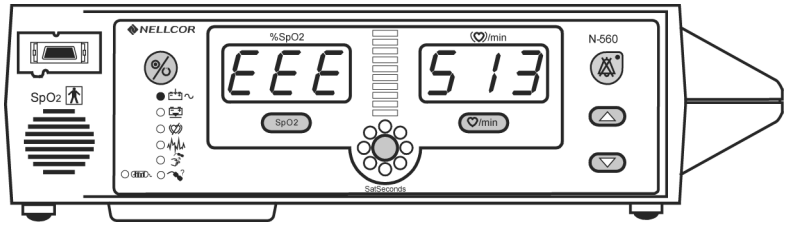
5. Once the display test portion of POST is complete, the N-560 software version is displayed for approximately 2 seconds.



Note: The device version illustrated is only a sample. The device version identifies the hardware configuration and the software revision.

Device version numbers are often needed when calling Nellcor's Technical Services Department, 1.800.635.5267, or your local Nellcor representative for technical assistance. Write down the numbers and have them available prior to requesting technical assistance.

6. If the N-560 detects an internal problem during the self-test, an alarm tone sounds and the N-560 displays an Error Code and the corresponding number. See *Troubleshooting* on page 75.



7. Upon successful completion of the POST, the N-560 sounds a one-second tone indicating that the N-560 has passed the test.

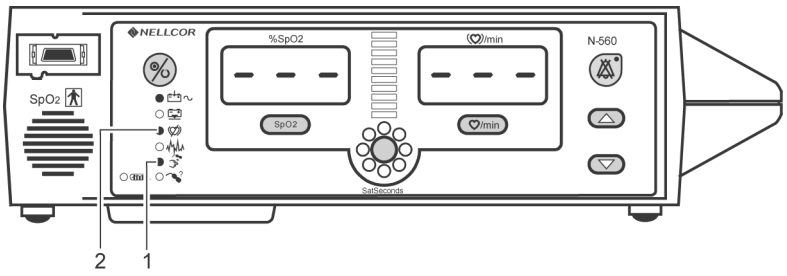
WARNING: If you do not hear the POST pass tone, do not use the N-560.

WARNING: Ensure that the speaker is clear of any obstruction. Failure to do so could result in an inaudible alarm tone.

Note: In addition to serving as the POST pass verification, the POST pass tone also functions as an audible confirmation that the speaker is performing properly. If the speaker does not function, the alarm sounds cannot be heard.

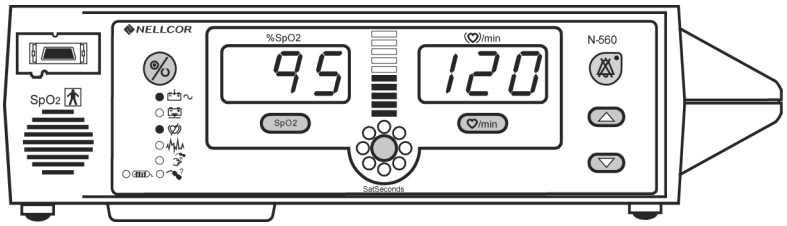
Sensor Attached

The **Pulse Search** indicator and the **Sensor Off** indicator light and the N-560 displays dashes in the %SpO_2 and **Pulse Rate** displays while the N-560 is searching for a valid pulse.

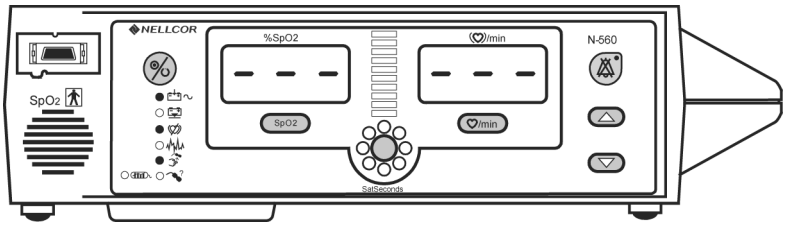


1. **Sensor Off** Indicator	2. **Pulse Search** Indicator

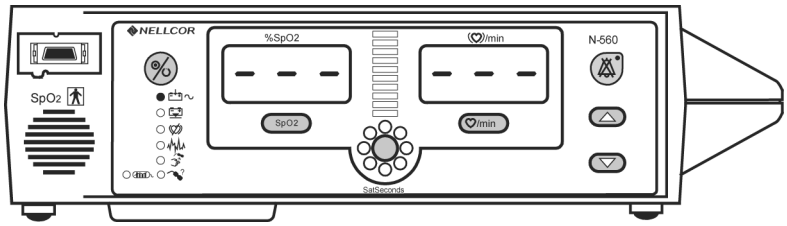
When a valid pulse is detected, the N-560 enters the Monitoring Mode and displays patient parameters. Look for movement of the blip bar and, if the pulse beep volume is not 0, listen for pulse beeps to verify that displayed measurement values are current and accurate.



When a sensor is connected to the N-560 and is not connected to a patient, the display reads dashes and the N-560 remains in the Pulse Search mode.



No Sensor Attached



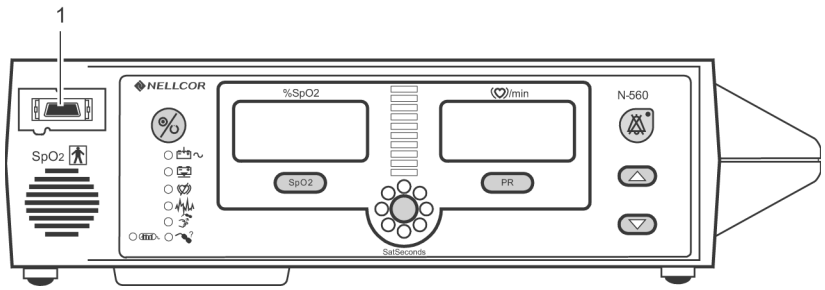
When the sensor is not attached the N-560 displays dashes (---) and the **Pulse Search** indicator is not lit, indicating that the N-560 failed to detect a sensor.

Sensor Message

The Sensor Message feature is an indication that the sensor position or site needs to be considered. The **Sensor Message** indicator lights when the N-560 cannot determine an SpO_2 level or a pulse rate. The Sensor Message recommendations for improving the signal are:

- Reposition sensor
- Check or change adhesive wrap
- Choose alternate site
- Warm site
- Cover sensor
- Use forehead, nasal, or ear sensor (adult patients only)
- Use *OXIMAX* adhesive sensor
- Secure cable
- Secure with headband (*MAX-FAST*)
- Remove nail polish
- Loosen sensor (too tight)
- Isolate external interference (electrosurgical device, cell phone)
- Clean site (MAX-R)

Setting the Pulse Beep Volume



1. SpO2 Sensor Port

WARNING: Use only Nellcor-approved sensors and sensor cables.

1. Connect a DOC-10 pulse oximetry cable to the SpO2 Sensor Port (1) on the front of the N-560.

2. Connect an SpO2 Sensor to the other end of the DOC-10 pulse oximetry cable.

3. Place the SpO2 Sensor on the patient or yourself.

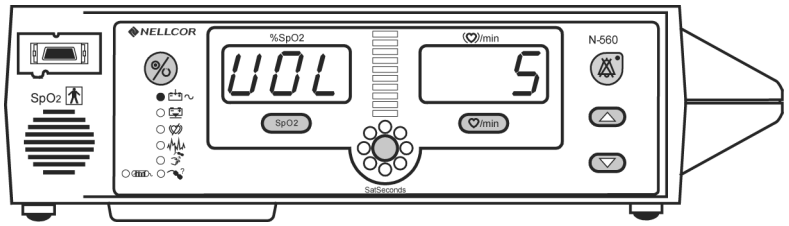
4. Turn on the N-560.

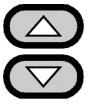
5. Press and hold the **Adjust Up** or **Adjust Down** button to increase or decrease the pulse beep tone volume.

Setting the Alarm Volume

With the N-560 in the normal monitoring mode:

1. Press and hold the **Alarm Silence** button until the alarm volume display appears.





2. While continuing to press the **Alarm Silence** button, press the **Adjust Up** button or **Adjust Down** button to increase or decrease the alarm volume.

Setting Alarm Silence Duration

Discussion

WARNING: Do not silence an audible alarm or decrease its volume if patient safety could be compromised.

Alarms can be silenced for a preset period called alarm silence duration. To view the current setting, press and hold the **Alarm Silence** button until 30 SEC, 60 SEC, 120 SEC, or OFF is displayed. To adjust the settings, press and hold the **Alarm Silence** button until 30 SEC, 60 SEC, 120 SEC, or OFF is displayed. Continue holding the **Alarm Silence** button, and use the **Adjust Up** button or **Adjust Down** button to increase or decrease the value. Possible values are 30, 60, 90, or 120 seconds, or OFF. The OFF selection is discussed under *Disabling Audible Alarms* on page 30.

If the **Alarm Silence** button is pressed during the alarm silence duration, the alarm silence duration is ended and the audible alarms are re-enabled.

Visual indications of an alarm condition cannot be turned off. For example, if the %SpO_2 lower alarm limit is exceeded, the alarm can be silenced for the alarm silence duration, but the %SpO_2 value will continue to flash.

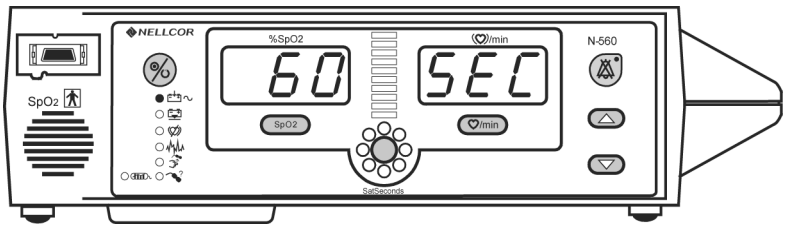
If the alarm condition is still present when the alarm silence duration has elapsed, the alarm will sound.

The power-on default setting for audible alarm silence duration is set at the factory to 60 seconds. The default setting can be adjusted by service personnel as described in the N-560 service manual.

Procedure

With the N-560 in the normal monitoring mode:

1. Press the **Alarm Silence** button until XX SEC is displayed. Durations are: OFF, 30, 60, 90, and 120 seconds.



Note: For steps 2 and 3, the **Adjust Up** and **Adjust Down** buttons must be pressed while pressing the **Alarm Silence** button.

2. While pressing the **Alarm Silence** button, press and hold the **Adjust Up** button to increase alarm silence duration to Off, 30, 60, 90, or 120 seconds.

3. While pressing the **Alarm Silence** button, press and hold the **Adjust Down** button to decrease alarm silence duration to OFF, 30, 60, 90, or 120 seconds.

Note: Releasing the **Adjust Up** or **Adjust Down** button sets the alarm silence duration.

Disabling Audible Alarms

Discussion

Setting the alarm silence duration to OFF means that the N-560 will produce no audible alarms.

Visual indications of an alarm condition are not affected by disabling the audible alarms.

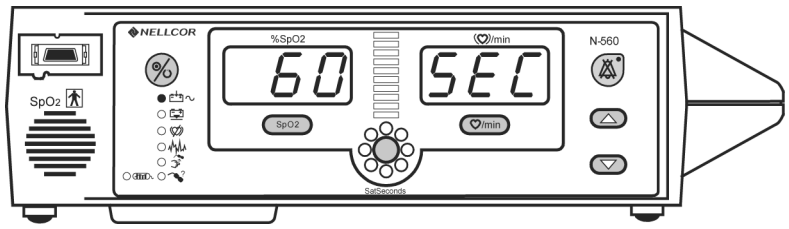
The ability to set the alarm silence duration to OFF can be enabled or disabled by qualified service personnel as described in the service manual.

WARNING: Do not silence the audible alarm or decrease its volume if patient safety could be compromised.

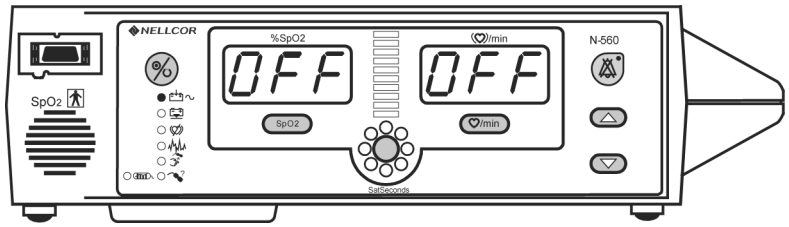
Procedure

With the N-560 in the normal monitoring mode:

1. Press the **Alarm Silence** button until XX SEC is displayed.



2. While pressing the **Alarm Silence** button, press and hold the **Adjust Up** button until OFF is displayed. Release buttons.



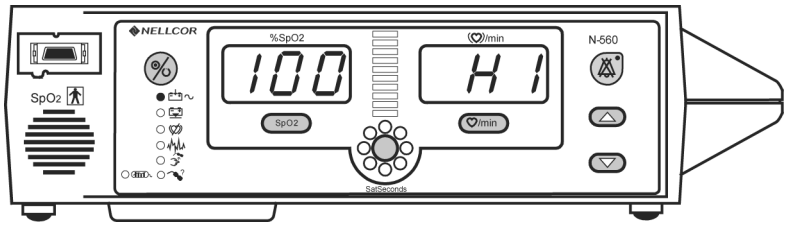
3. The **Alarm Silence** indicator will flash, indicating that the alarm sounds are disabled. The N-560 will sound three beeps approximately every three minutes to warn the user that the alarm sound has been silenced.

Verify Patient Settings

With the N-560 in the normal monitoring mode:

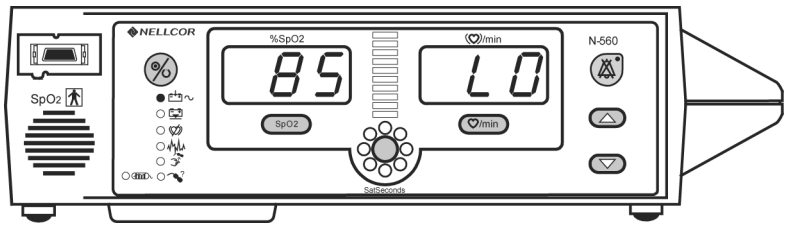
SpO2

1. Press the **SpO2 Alarm Limit** button to view the current %SpO2 upper alarm limit.



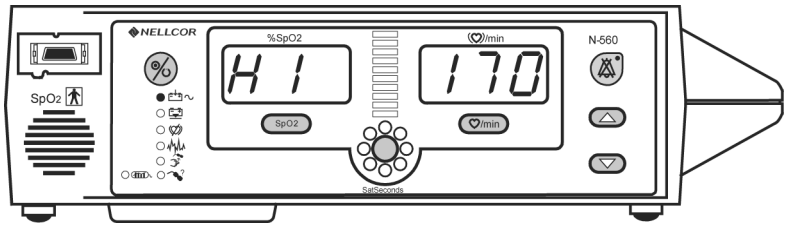
SpO2 SpO2

2. Press the **SpO2 Alarm Limit** button twice to view the current %SpO2 lower alarm limit.

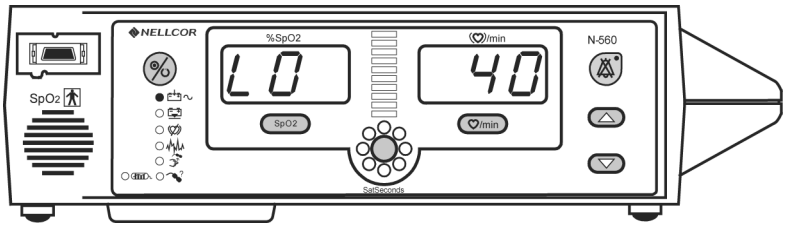


/min

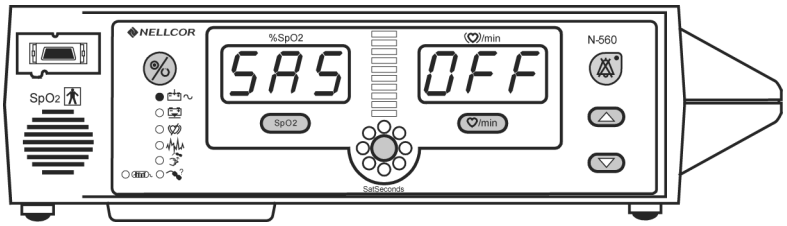
3. Press the **Pulse Rate Alarm Limit** button to view the current Pulse Rate upper alarm limit.



4. Press the **Pulse Rate Alarm Limit** button twice to view the current Pulse Rate lower alarm limit.



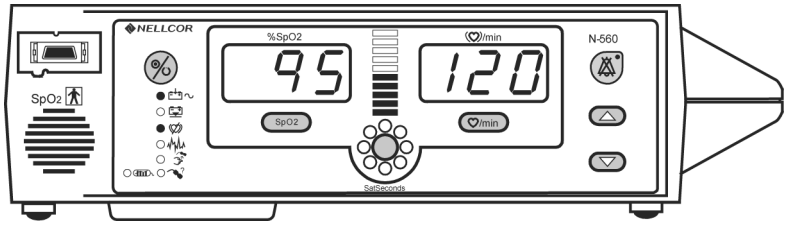
5. Press the **SatSeconds Alarm Limit** button to view the current *SatSeconds* setting.



Note: The *SatSeconds* (12 O'clock) indicator lights, indicating that *SatSeconds* units are being reviewed. The *SatSeconds* (12 O'clock) indicator lights for all *SatSeconds* except Off.

Alarm Limits Changed Indicator

If an alarm limit is changed from the N-560's power-on default setting, a decimal point appears after the applicable displayed value, during patient monitoring and when alarm limits are viewed. The decimal point remains on the display until the N-560 is turned off or the limit is returned to the default value.



Alarm limits that have been changed from the default setting are identified by a decimal point (.) after the displayed reading (%SpO_2 or Pulse Rate).

Setting Alarm Limits

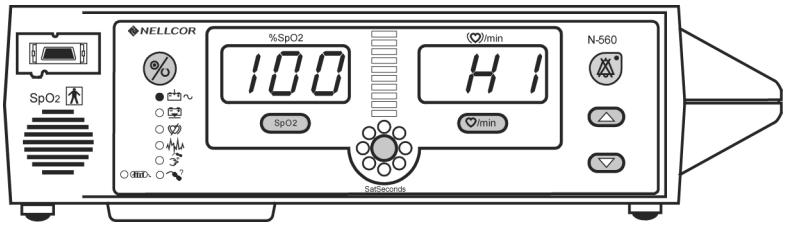
Discussion

Alarm limits determine the upper and lower points of patient data at which the N-560 will sound an alarm.

Procedure

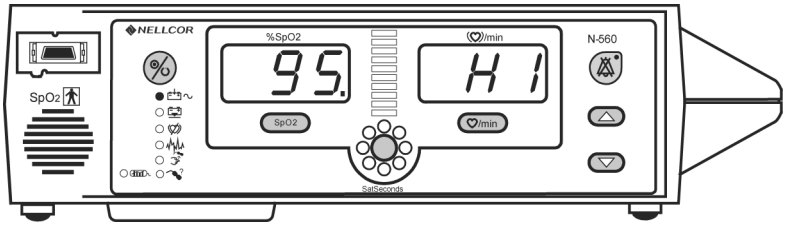
With the N-560 in the normal monitoring mode:

1. Press **SpO2 Alarm Limit** button to view the current %SpO_2 upper alarm limit.

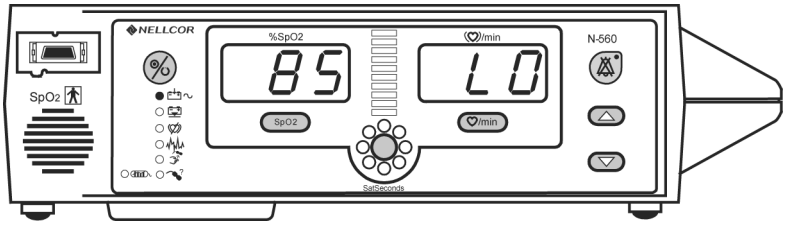


2. Press the **Adjust Up** button or **Adjust Down** button to increase or decrease the alarm limit setting.

Note: When an alarm limit is changed from power-on default, the N-560 displays a decimal point (.) after the changed parameter.

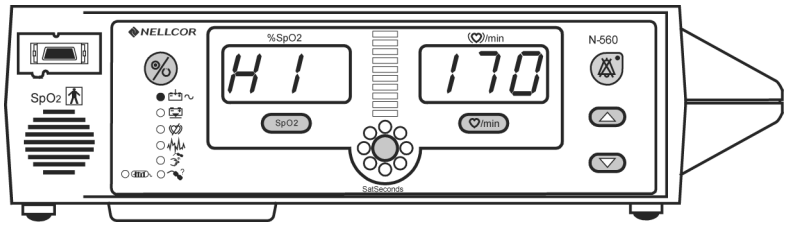


3. Press the **SpO2 Alarm Limit** button twice to view the current %SpO2 lower alarm limit.

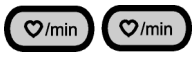


4. Press the **Adjust Up** button or **Adjust Down** button to increase or decrease the alarm limit setting.

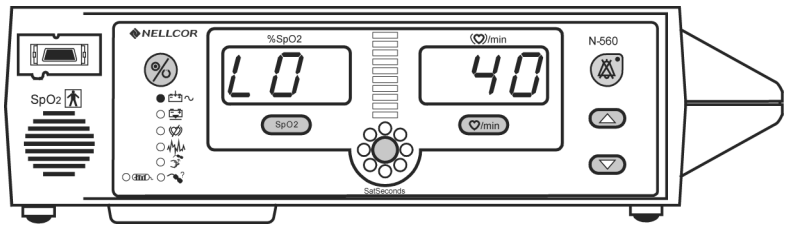
5. Press the **Pulse Rate Alarm Limit** button to view the current upper alarm limit for Pulse Rate.



6. Press the **Adjust Up** button or **Adjust Down** button to increase or decrease the alarm limit setting.



7. Press the **Pulse Rate Alarm Limit** button twice to view the current lower alarm limit for Pulse Rate.



8. Press **Adjust Up** button or **Adjust Down** button to increase or decrease the alarm limit setting.

Setting *SatSeconds* Duration

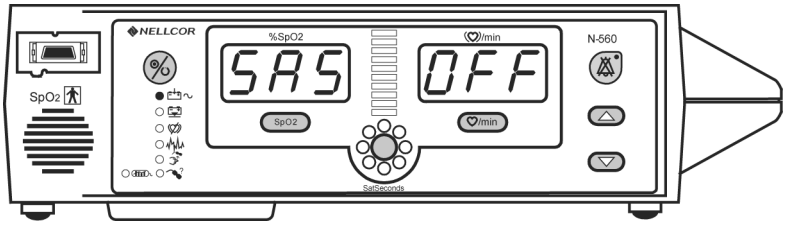
Discussion

Refer to *Describing SatSeconds* on page 87 for a description of the *SatSeconds* function.

Procedure

With the N-560 in the normal monitoring mode:

1. Press the **SatSeconds Alarm Limit** button. The current *SatSeconds* setting is displayed.



Note: The possible settings for *SatSeconds* are Off, 10, 25, 50, and 100 seconds.

2. Press the **Adjust Up** button or **Adjust Down** button to select the desired *SatSeconds* setting.

Setting the Data Port Baud Rate

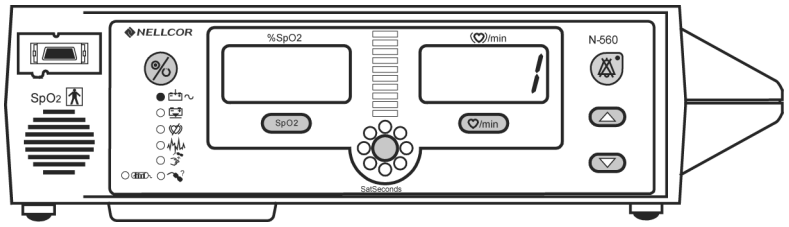
Discussion

The baud rate determines the speed at which the N-560 sends data to the attached equipment (printer or computer). The baud rate is determined by the capabilities of the attached equipment.

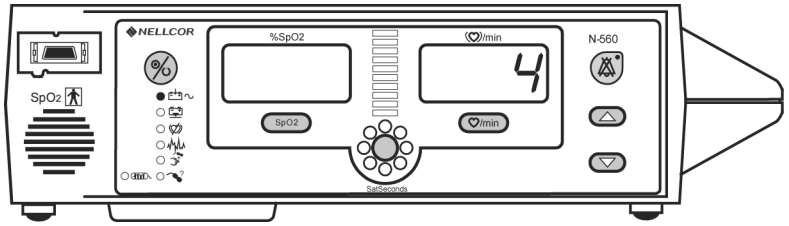
Procedure

With the N-560 in the normal monitoring mode:

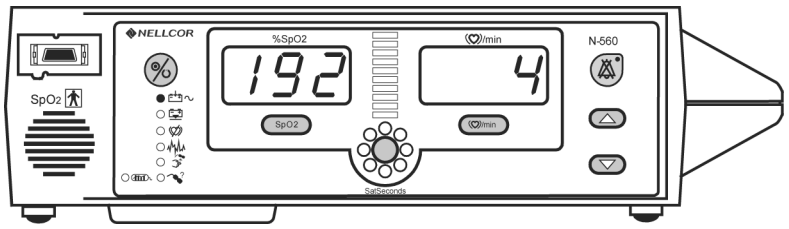
1. Simultaneously, press the **SpO2 Alarm Limit** button and **Pulse Rate Alarm Limit** button for 3 seconds. Menu option 1 will be displayed.



2. Press the **Adjust Up** button until menu item option 4 is displayed.



3. Press the **SatSeconds Alarm Limit** button. Current baud rate is displayed.



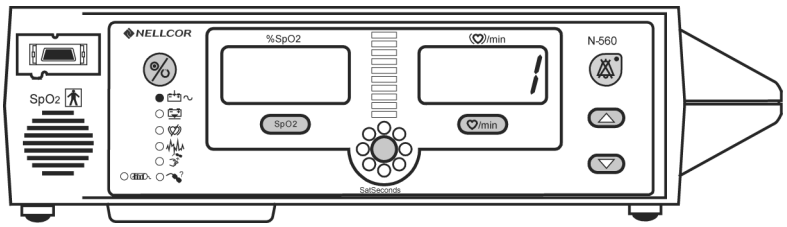
Press the **Adjust Up** button or **Adjust Down** button to select the desired baud rate. Possible settings are:

- 24 (2,400 bps)
- 96 (9,600 bps)
- 192 default (19,200 bps).

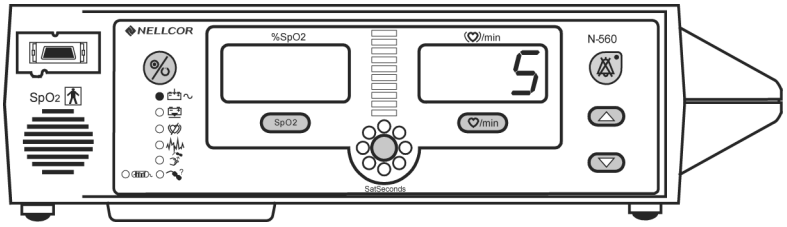
Setting the Data Port Protocol

With the N-560 in the normal monitoring mode:

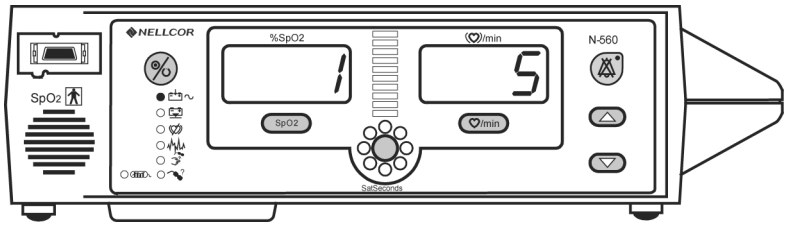
1. Simultaneously, press the **SpO2 Alarm Limit** button and **Pulse Rate Alarm Limit** button for three seconds. Menu option 1 will be displayed.

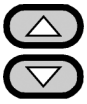


2. Press the **Adjust Up** button until menu item option 5 is displayed.



3. Press the **SatSeconds Alarm Limit** button. Current protocol is displayed.





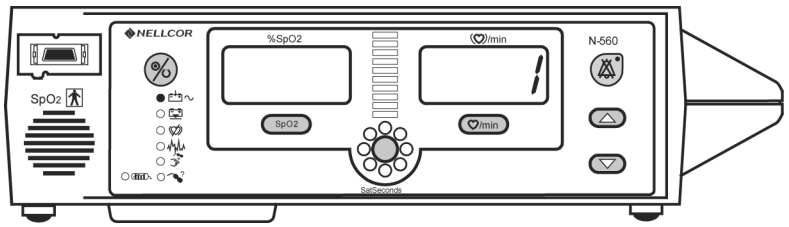
4. Press the **Adjust Up** button or **Adjust Down** button to select the desired protocol. Possible settings are:

   1 - ASCII
   2 - External equipment communications. Refer to the external equipment manuals for the interfacing instructions.

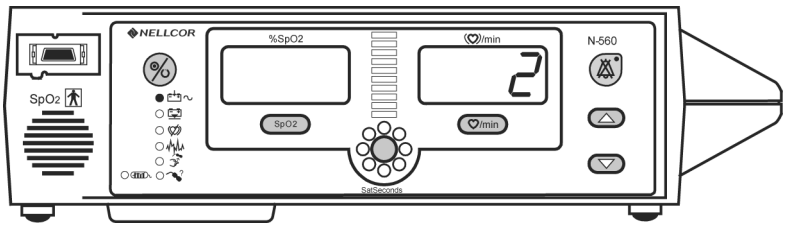
Clearing Trend Information

With the N-560 in the normal monitoring mode:

1. Simultaneously press and hold the **SpO2 Alarm Limit** button and **Pulse Rate Alarm Limit** button for at least three seconds. Option 1 will be displayed.



2. Press the **Adjust Up** button to select Option 2.



3. Press the **SatSeconds Alarm Limit** button to clear the trend data.

4. The N-560 emits 3 beeps, indicating that data is cleared.

N-560 Trend

Trend Data Operation

From the initial measurement of a patient, trend data (a data point) is stored in memory every 4 seconds. Up to 50 alarm limit changes can also be stored in trend data. The N-560 can store up to 24 hours of trend data.

The N-560 trend data will be lost if the coin cell battery fails or is removed. The coin cell battery is located on the main circuit board.

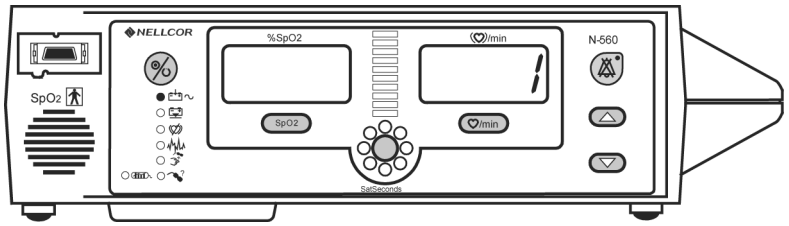
CAUTION: Changing alarm limit settings uses trend memory space. Change alarm limits only as needed.

Note: Trend memory always contains the most recent 24 hours of data, with newly collected data overwriting the oldest data on a rolling basis. The N-560 continues to record data points as long as the N-560 is powered on and an initial patient measurement has been made, with “blank” data points collected if no sensor is connected to the N-560 or patient. “Blank” data will overwrite older patient data if the memory becomes full. Therefore, if you want to save old patient data, it is important that you turn your N-560 off when you are not monitoring a patient, and that you download the trend memory before it fills up and overwrites the old data with new data (or “blank” data).

Trend Data

Trend data information may be retrieved or cleared through the N-560 data port using options available in a display menu.

To access the menu options, simultaneously press the **SpO2 Alarm Limit** and **Pulse Rate Alarm Limit** buttons until Option 1 appears on the display.



Then, using the **Adjust Up** button and **Adjust Down** button, you may scroll through the available menu options as follows:

#1: Trend Print

Allows printing of the existing trend data. The output may be viewed on a PC using the Hyper Terminal program. You must press the **SatSeconds Alarm Limit** button to initiate printing. Refer to *Trend Data Printout* on page 57.

#2: Trend Clear

Clears the existing trend data. To activate, press the **SatSeconds Alarm Limit** button.

#3: Not Used

#4: Baud Rate

Allows the interconnection to various printers. Refer to *Setting the Data Port Baud Rate* on page 37. The baud rate selections are:

- 24 (2,400 baud rate)
- 96 (9,600 baud rate)
- 192 default (19,200 baud rate)

#5: Data Port Printout

Selections are as follows:

Option 1

Printout in ASCII characters.

Option 2

External equipment communications. Refer to the external equipment manual for the interfacing instructions.

Using the Data Port

Overview

Patient data can be obtained through the data port on the back of the N-560 by connecting it to an attached PC or serial printer.

When connecting the N-560 to a printer or PC, verify proper operation before clinical use. Both the N-560 and the printer or PC must be connected to a grounded AC outlet. The N-560 protocol setting must be ASCII.

Any printer or PC connected to the N-560's data port must be certified according to IEC Standard 60950. All combinations of equipment must be in compliance with IEC Standard 60601-1-1 systems requirements. Anyone who connects a printer or PC to the data output port configures a medical system and is therefore responsible for ensuring that the system complies with the requirements of system standard IEC Standard 60601-1-1 and the electromagnetic compatibility system standard IEC Standard 60601-1-2.

Connecting to the Data Port

The N-560 data port may be connected to the printer or PC by using a cable terminated with an AMP connector (AMP part number 747538-1), ferrule (AMP part number 1-747579-2), and compatible pins (AMP part number 66570-2). The cable should be no more than 25 feet (7.6 meters) in length. The external ITE (Information Technology Equipment) device must be certified to UL-1950 or IEC-60950.

The cable used must have a braided shield providing 100% coverage, such as a Belden cable (Belden part number 9609) or equivalent. The shield must have a 360-degree connection to the metal shell on the N-560's DB-15 connector and to the connector on the PC or serial printer. Do not create sharp bends in the cable, as this may tear or break the shielding.

No hardware flow control is used. However, in the ASCII mode, XON/XOFF flow control is supported.

Data Port Pinouts

TXD represents the Transmit Data line, and RXD is the Receive Data line.

The pinouts for the data port are listed in Table 1.

Table 1: Data Port Pinouts

Pin	Signal Name
1	RXD+ (RS-422 positive input)
2	RXD (RS-232 input)
3	TXD (RS-232 output)
4	TXD+ (RS-422 positive output))
5	Signal Ground (isolated from Earth Ground)
6	NC (No connection)
7	Normally Open (relay closure nurse call, normally open)
8	Normally Closed (relay closure nurse call, normally closed)
9	RXD- (RS-422 negative output)
10	Signal Ground (isolated from earth ground)
11	Nurse Call (RS-232 level output)
12	TXD- (RS-422 negative output)
13	NC
14	NC
15	Nurse Call Common

The pin layouts (as viewed from the rear panel of the N-560) are illustrated in Figure 3. The conductive shell is connected to earth ground when connected to a PC or printer.

Figure 3: Data Port Pin Layout

Pins 2, 3, 5, and 11 provide data in RS-232 format.

Pins 1, 4, 9, and 12 provide data in RS-422 format. TXD+ and TXD- are the differential transmit data pair. RXD+ and RXD- are the differential receive pair.

Data Port Setup

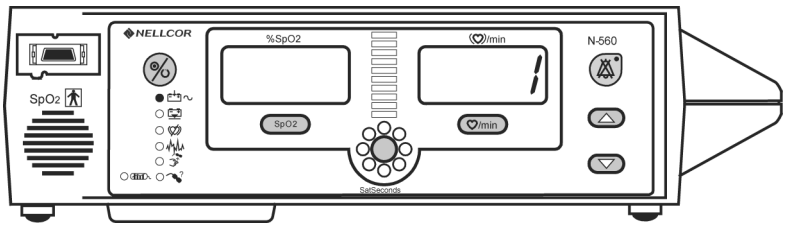
Discussion

Use the Data Port Setup procedure to configure the N-560 data port baud rate and protocol.

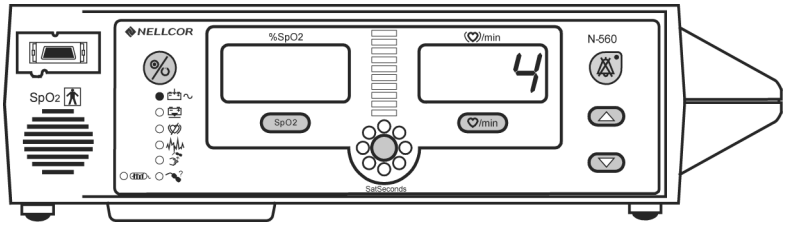
Procedure

With the N-560 in the normal operating mode:

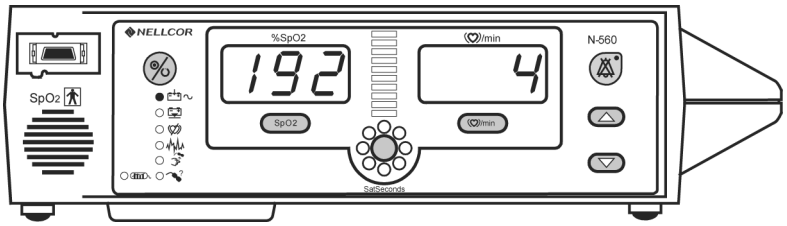
1. Simultaneously press and hold the **SpO2 Alarm Limit** button and **Pulse Rate Alarm Limit** button for at least 3 seconds. Option 1 will be displayed.



2. Press the **Adjust Up** button until Option 4 is displayed.



3. Press the **SatSeconds Alarm Limit** Button to select Option 4. The selected baud rate will be displayed.

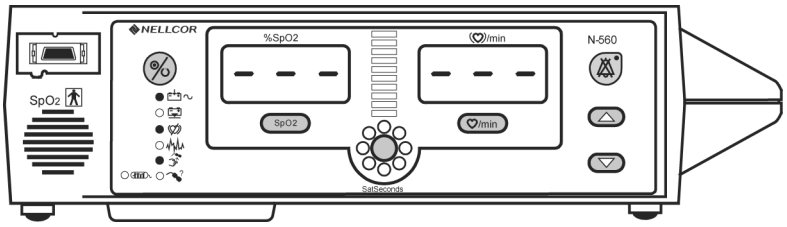


Note: The available selections are:

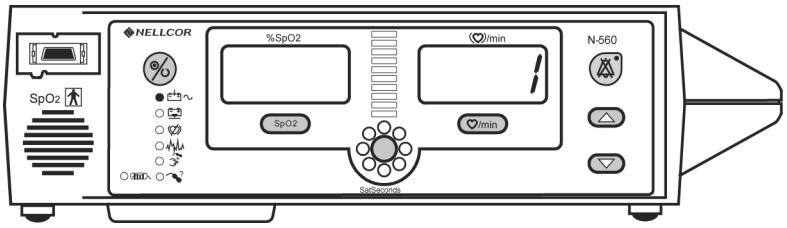
- 24 = 2400 baud rate
- 96 = 9600 baud rate
- 192 = 19200 baud rate

4. Press the **Adjust Up** button or the **Adjust Down** button to select the desired baud rate.

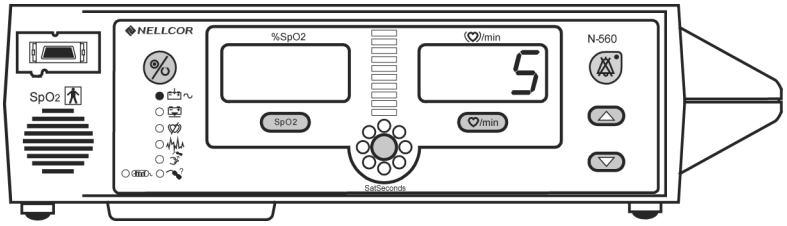
5. Press the **SatSeconds Alarm Limit** button to save the desired baud rate.



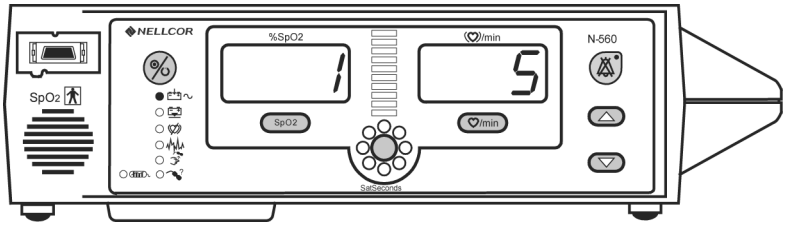
6. Simultaneously press and hold the **SpO2 Alarm Limit** button and **Pulse Rate Alarm Limit** button for at least 3 seconds. Option 1 will be displayed.



7. Press the **Adjust Up** button until Option 5 is displayed.



8. Press the **SatSeconds Alarm Limit** Button to select Option 5. The selected protocol will be displayed.

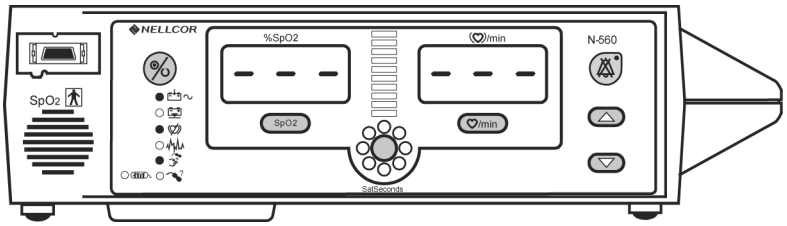


Note: The available selections are:

- 1 = Real time ASCII
- 2 = External equipment communications. Refer to the external equipment manuals for the interfacing instructions.

9. Press the **Adjust Up** button or the **Adjust Down** button to display the desired protocol.

10. Press the **SatSeconds Alarm Limit** button to save the desired protocol.



Nurse Call Interface

WARNING: The nurse call feature should not be used as the primary source of alarm notification. The audible and visual alarms of the pulse oximeter, used in conjunction with clinical signs and symptoms, are the primary sources for notifying medical personnel that an alarm condition exists.

WARNING: The nurse call feature is not functional whenever the pulse oximeter alarms are silenced.

Caution: The nurse call function needs to be tested after it has been set up in your facility. The nurse call feature should be tested whenever setting up the N-560 pulse oximeter in a location that uses nurse call. If an attached *OxiMax* sensor is disconnected from the patient, the N-560 remains in the Pulse Search Mode for awhile, then the N-560 displays "--- " (3 dashes) in the %SpO_2 and pulse rate display. One way to test the nurse call function is to create an alarm condition (for example, sensor disconnect) and verify that your facility's nurse call system is activated.

The nurse call feature of the N-560 is operational when the N-560 is powered by AC power or battery power. The nurse call feature of the N-560 works in conjunction with the nurse call system of your institution when the N-560 sounds an audible alarm.

The N-560 provides two different types of nurse call interfaces: an RS-232 format and relay closure. Both interfaces function when the N-560 is operating either on AC power or battery power.

The remote location is signaled anytime there is an audible alarm. If the audible alarm has been turned off or silenced, the nurse call function is also turned off.

Pin 11 on the data port is the RS-232 level nurse call signal and pin 5 or 10 is ground (see Table 1 on page 48). When there is no alarm condition, the voltage between pins 10 and 11 is -5 to -12 VDC. Whenever the N-560 is in an alarm condition, the output between pins 10 and 11 is +5 to +12 VDC. This is the default condition (normally low). There is a service menu to change the default condition. Refer to the N-560 service manual for the procedure.

Pins 7 and 15 provide a relay that closes when an alarm is sounding on the N-560. Pins 8 and 15 provide a relay that opens when an alarm is sounding. Pin 15 is a common lead for both relays.

Note: When the relay is closed there is approximately 27 ohms of resistance.

Setting Nurse Call RS-232 Polarity

The nurse call polarity can be set to a high signal on an N-560 alarm condition or a low signal on an N-560 alarm condition. Refer to the N-560 service manual for setting the Nurse Call RS-232 polarity.

Setting Nurse Call Relays Normally Open/Closed

Data port pins 7 and 15 provide a relay that closes (nominally 27 ohms) when an alarm is sounding on the N-560. Pins 8 and 15 provide a relay that opens when an alarm is sounding. Pin 15 is a common lead for both relays. The relay operates whether the N-560 is operating on AC power or battery.

Printing

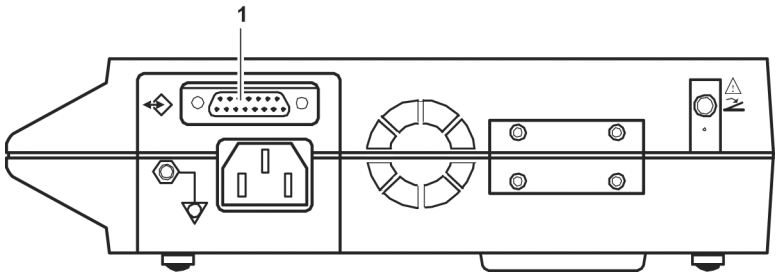
Printing N-560 Real-Time Data

Real-time data is continuously sent to the data port on the back of the N-560. Patient data can be obtained through the data port by connecting to a computer or serial printer. When a real-time printout or display is being transmitted to a printer or computer, a new line is printed/displayed every 2 seconds. Column headings are printed/displayed every 25 lines, or if one of the values in the column heading is changed.

Note: If the data output stops transmitting, the N-560 must be turned off and then turned back on.

When connecting the N-560 to a printer or computer, verify proper operation before clinical use. Both the N-560 and the printer or PC must be connected to a grounded AC outlet.

Any printer or computer connected to the N-560's data port must be certified according to IEC Standard 60950. All combinations of equipment must be in compliance with IEC Standard 60601-1-1 systems requirements. Anyone who connects a printer or PC to the data output port configures a medical system and is therefore responsible that the system complies with the requirements of system standard IEC Standard 60601-1-1 and the electromagnetic compatibility system standard IEC Standard 60601-1-2.



1. Data Port Connector

1. Connect the serial printer to the N-560's Data Port connector (1).

2. Turn on the printer.

3. Connect the N-560 to an AC outlet.

4. Turn on the N-560.

The printer will start printing real time trend data or the PC will start displaying real time data at a rate of one line every 2 seconds.

N-560 VERSION 1.00.00 CRC:XXXX SpO2 Limit: 85-100% PR Limit: 40-170 bpm

ADULT 0 SAT-S

TIME	%SpO2	BPM	PA	Status
02-Jan-06 16:00:00	100	120	220	
02-Jan-06 16:00:02	100	124	220	
02-Jan-06 16:00:04	100	170	220	
02-Jan-06 16:00:06	100	120	220	
02-Jan-06 18:00:43	---	---	---	SD
02-Jan-06 18:00:45	---	---	---	SD

N-560 VERSION 1.00.00 CRC:XXXX SpO2 Limit: 80-100% PR Limit: 40-170 bpm

ADULT 0 SAT-S

TIME	%SpO2	BPM	PA	Status
02-Jan-06 18:24:24	---	---	---	SD
02-Jan-06 18:24:26	---	---	---	SD
02-Jan-06 18:24:28	98	100	140	
02-Jan-06 18:24:30	98	181*	190	PH
02-Jan-06 18:24:32	99	122	232	

Figure 4: Real-Time Data Printout

Trend Data Printout

The format of data displayed when a trend printout is requested is the same as the real-time data. The only differences are that “TREND” is displayed in the top row instead of the “CRC: XXXX” software verification number and there is no “Status” column.

Readings are displayed in 4-second intervals. The values on each row are an average for the 4-second period.

At the end of the printout, an “Output Complete” line indicates that the transmission was successful. If the “Output Complete” line is not present, a corruption of the data may have been detected and the data should be ignored.

N-560 VERSION 1.00.00 TREND SpO2 Limit: 85-100% PR Limit: 40-170 bpm

ADULT 0 SAT-S

TIME	%SpO2	BPM	PA
02-Jan-06 21:26:53	98	110	53
02-Jan-06 21:26:57	98	110	53
02-Jan-06 21:30:01	98	110	53

N-560 VERSION 1.00.00 TREND SpO2 Limit: 80-100% PR Limit: 40-170 bpm

ADULT 0 SAT-S

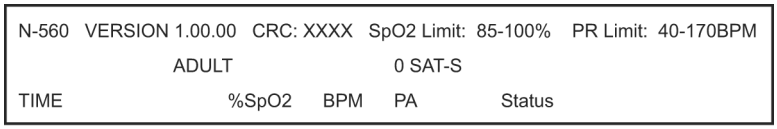
TIME	%SpO2	BPM	PA
02-Jan-06 21:30:05	98	110	53
02-Jan-06 21:30:09	95	110	51
02-Jan-06 21:30:13	93	115	50
02-Jan-06 21:30:17	91	118	49
02-Jan-06 21:30:21	85	122	47
02-Jan-06 21:30:25	80	124	42
02-Jan-06 21:30:29	78*	125	41
02-Jan-06 21:30:33	78*	127	41

Output Complete

Figure 5: Trend Data Printout

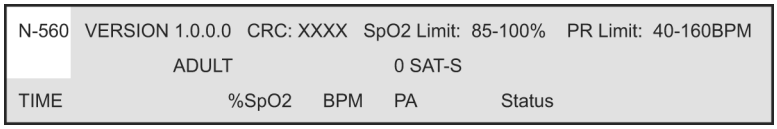
Once a trend printout has begun, the N-560 must be turned off and back on again before a new trend printout can begin.

Column Headings



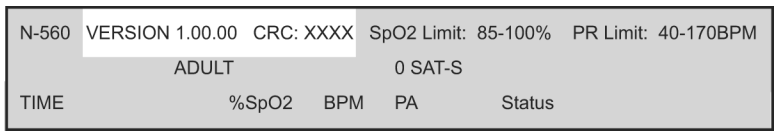
Column headings are displayed or printed after every 25 lines, or if one of the values in the column heading changes.

Data Source



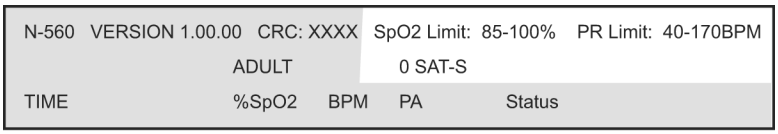
Data in the highlighted box above represents the model number of the N-560, in this case the N-560.

Device/Software Revision Level



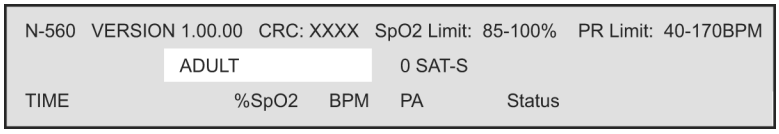
The next data field tells the user the software level (Version 1.00.00) and a software verification number (CRC: XXXX). Neither of these numbers should change during normal operation. The numbers may change if the N-560 is serviced and receives a software upgrade.

Alarm Limits



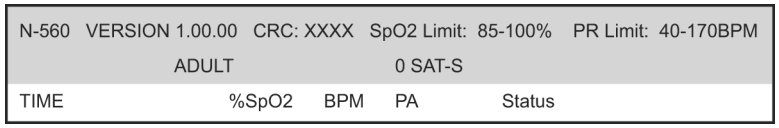
The last data field in the top line indicates the upper and lower alarm limits for %SpO_2 and for the pulse rate (PR), and the *SatSeconds* alarm setting (OFF). The *SatSeconds* setting may be OFF, 10, 25, 50, or 100 depending on the *SatSeconds* alarm setting. In the example above, the low alarm limit for SpO_2 is 85% and the upper alarm limit is 100%. Pulse Rate alarm limits are 40 to 170 bpm. *SatSeconds* alarm limit is set to off.

N-560 Mode



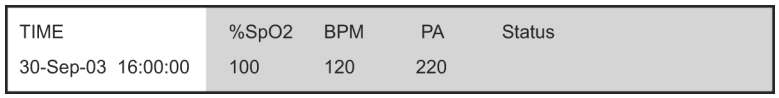
The N-560 mode is ADULT.

Data Column Headings



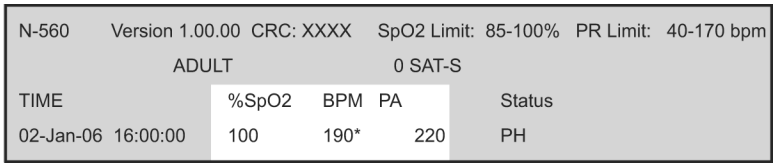
Actual column headings are in the third row of the column heading line. Patient data that is presented in the chart, from left to right, are the time that the patient data on the row was obtained, the current %SpO_2 value being measured, the current Pulse Rate in beats per minute (bpm), the current Pulse Amplitude (PA), and the operating status of the N-560.

Time



The Time column represents the N-560 real-time clock. Refer to the N-560 service manual to set the N-560 real-time clock.

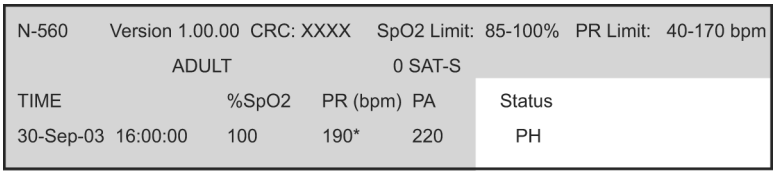
Patient Data


N-560 Version 1.00.00 CRC: XXXX SpO2 Limit: 85-100% PR Limit: 40-170 bpm
ADULT 0 SAT-S
TIME %SpO2 BPM PA Status
02-Jan-06 16:00:00 100 190* 220 PH

Patient data is highlighted in the display above. Parameter values are displayed directly beneath the heading for each parameter. In this example, the %SpO_2 is 100, and the pulse rate is 190 beats per minute. An asterisk indicates that the parameter is outside the set limits. If no data for a parameter is available, three dashes (- - -) are displayed.

PA represents pulse amplitude. The number can range from 0 to 254. There are no alarm parameters for this value. It can be used for trending information as an indication of a change in pulse volume, relative pulse strength, or circulation.

Operating Status


N-560 Version 1.00.00 CRC: XXXX SpO2 Limit: 85-100% PR Limit: 40-170 bpm
ADULT 0 SAT-S
TIME %SpO2 PR (bpm) PA Status
30-Sep-03 16:00:00 100 190* 220 PH

The Status column indicates alarm conditions and operating status of the N-560. In this example, Pulse High (PH) means that the pulse rate upper alarm limit has been exceeded. The status codes are listed in the following table. As many as four codes can be displayed at one time in the Status column.

Code	Meaning
AO	**A**larm **O**ff
AS	**A**larm **S**ilence
LB	**L**ow **B**attery
LM	Loss of Pulse w/**I**nterference
LP	**L**oss of **P**ulse
MO	**I**nterference Detected
PH	**P**ulse Rate Upper Limit Alarm
PL	**P**ulse Rate **L**ower Limit Alarm
PS	**P**ulse **S**earch
SH	**S**aturation Upper Limit Alarm
SL	**S**aturation **L**ower Limit Alarm
SD	**S**ensor **D**isconnect
SO	**S**ensor **O**ff

Note: A sensor disconnect and sensor off will also cause three dashes (- - -) to be displayed in the patient data section of the printout.

Sensors and Accessories

Selecting a Sensor

WARNING: Before use, carefully read the sensor directions for use, including all warnings, cautions, and instructions.

WARNING: Do not use a damaged sensor or pulse oximetry cable. Do not use a sensor with exposed optical components.

WARNING: Use only Nellcor sensors and pulse oximetry cables with the N-560. Other sensors or pulse oximetry cables may cause improper N-560 performance.

WARNING: Use only one pulse oximetry cable to increase the length of the sensor. Use of more than one pulse oximetry cable may have an adverse effect on performance. Do not attach any cable that is intended for computer use to the sensor port.

WARNING: Pulse oximetry readings and pulse signal can be affected by certain ambient environmental conditions, sensor application errors, and certain patient conditions.

WARNING: Tissue damage can be caused by incorrect application or duration of use of an SpO_2 sensor. Inspect the sensor site as directed in the sensor directions for use.

WARNING: Do not immerse or wet the sensor.

When selecting a sensor, consider the patient's weight and activity level, the adequacy of perfusion and the available sensor sites, the need for sterility, and the anticipated duration of monitoring. For more information, refer to Table 2 or contact your local Nellcor representative.

For a complete and up-to-date listing of all sensors applicable to the N-560, refer to the Sensor Accuracy Grid posted on the Internet at:

http://www.mallinckrodt.com/respiratory/resp/Serv_Supp/ProductManuals.html

Follow the sensor sterilization procedures in the applicable sensor directions for use (DFU).

Table 2: Nellcor Oximetry Sensor Models and Patient Weights

OxiMax Sensor	Model	Patient Size[1]
OxiMax MAX-FAST adhesive forehead sensor, single-patient-use	MAX-FAST	>10 kg (>22 lbs)
OxiMax Softcare nonadhesive sensor, single-patient-use, preterm infant	SC-PR	<1.5 kg (<3.3 lbs)
OxiMax Softcare nonadhesive sensor, single-patient-use, neonate	SC-NEO	1.5 to 5 kg (3.3 to 11 lbs)
OxiMax Softcare nonadhesive sensor, single-patient-use, adult	SC-A	>40 kg (>88 lbs)
OxiMax adhesive sensor, single-patient-use, adult	MAX-A	>30 kg (>66 lbs)
OxiMax adhesive sensor, single-patient-use, adult, longer cable 36 inches (91.44 cm)	MAX-AL	>30 kg (>66 lbs)
OxiMax adhesive sensor, single-patient-use, neonatal/adult	MAX-N	<3 kg or >40 kg (<6.6 lbs or >88 lbs)
OxiMax adhesive sensor, single-patient-use, pediatric	MAX-P	10 to 50 kg (22 to 110 lbs)
OxiMax adhesive sensor, single-patient-use, infant	MAX-I	3 to 20 kg (6.6 to 44 lbs)

Table 2: Nellcor Oximetry Sensor Models and Patient Weights (Cont.)

OxiMax Sensor	Model	Patient Size[1]
OxiMax adhesive sensor, single-patient-use, adult nasal	MAX-R	>50 kg (>110 lbs)
OxiMax OxiCliq® nonadhesive sensor, single-patient-use, adult, reusable cable	OxiCliq A	>30 kg (>66 lbs)
OxiMax OxiCliq nonadhesive sensor, single-patient-use, neonatal/adult, reusable cable	OxiCliq N	<3 kg or >40 kg (<6.6 lbs or >88 lbs)
OxiMax OxiCliq nonadhesive sensor, single-patient-use, pediatric, reusable cable	OxiCliq P	10 to 50 kg (22 to 110 lbs)
OxiMax OxiCliq nonadhesive sensor, single-patient-use, infant, reusable cable	OxiCliq I	3 to 20 kg (6.6 to 44 lbs)
OxiMax Durasensor® finger-clip sensor, reusable, adult	DS-100A	>40 kg (>88 lbs)
OxiMax Oxiband® sensor, reusable, neonatal/adult	OXI-A/N	<3 kg or >40 kg (<6.6 lbs or >88 lbs)
OxiMax Oxiband sensor, reusable, pediatric/infant	OXI-P/I	3 kg to 40 kg (6.6 lbs to 88 lbs)
OxiMax Dura-Y® multisite sensor, reusable	D-YS	>1 kg (>2.2 lbs)
For use with the Dura-Y sensor:		
• Ear clip (Reusable, non-sterile)	D-YSE	>30 kg (>66 lbs)
• *Pedi-Check*™ pediatric spot-check clip (Reusable, non-sterile)	D-YSPD	3 kg to 40 kg (6.6 lbs to 88 lbs)

1. The symbol > means *greater than* and the symbol < means *less than*.

Biocompatibility Testing

Biocompatibility testing has been conducted on Nellcor *OxiMax* sensors in compliance with ISO 10993-1, Biological Evaluation of Medical Devices, Part 1: Evaluation and Testing. The *OxiMax* sensors have passed the recommended biocompatibility testing and are therefore in compliance with ISO 10993-1.

Optional Accessories

Several optional accessories are offered with the N-560. Contact Nellcor's Technical Services Department, 1.800.635.5267, or your local Nellcor representative for information about these accessories.

- Visual alarm indicator
- Pole mount bracket

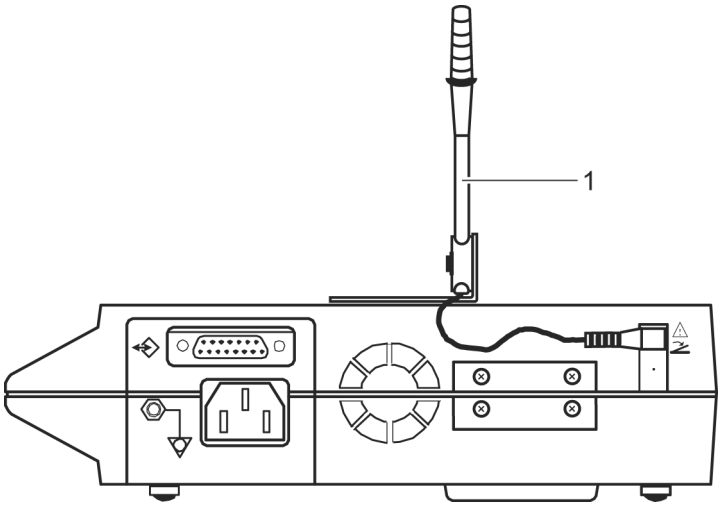
Accessories for the N-560 are listed on the Internet at:

http://www.mallinckrodt.com/respiratory/resp/Serv_Supp/Apartweb/main/

Visual Alarm Indicator

An optional visual alarm indicator is available for the N-560. The visual alarm indicator mounted on the top of the N-560 with double-back tape. The visual alarm indicator is connected to the rear of the N-560.

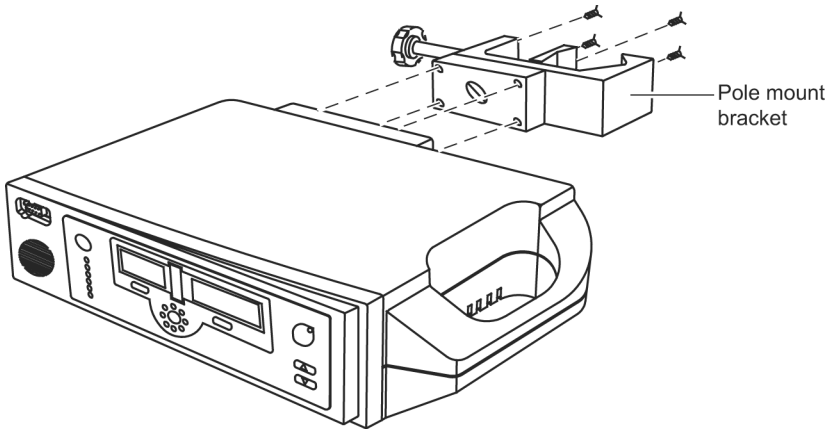
CAUTION: The N-560 must be turned off when connecting or disconnecting the visual alarm indicator.



1. Visual alarm indicator

Pole Mount Bracket

An optional pole mount bracket is available for the N-560. The pole mount bracket may be used to attach the N-560 to an IV pole. The pole mount bracket is attached to the rear of the N-560.



Performance Considerations

WARNING: Pulse oximetry readings and pulse signals can be affected by certain ambient environmental conditions, sensor application errors, and certain patient conditions. See the appropriate sections of the manual for specific safety information.

Performance Verification

The performance of the N-560 can be verified by following the procedures outlined in the Performance Verification section of the N-560 service manual. Qualified service personnel should perform these procedures before using the N-560 for the first time in a clinical setting.

N-560 Performance Considerations

Certain patient conditions can affect the measurements of the N-560 and cause the loss of the pulse signal.

Inaccurate measurements can be caused by:

- excessive patient movement
- venous pulsations
- intravascular dyes, such as indocyanine green or methylene blue
- defibrillation

Dysfunctional Hemoglobins

Dysfunctional hemoglobins such as carboxyhemoglobin, methemoglobin, and sulphemoglobin are unable to carry oxygen. SpO_2 readings may appear normal; however, a patient may be hypoxic because less hemoglobin is available to carry oxygen. Further assessment beyond pulse oximetry is recommended.

Anemia

Anemia causes decreased arterial oxygen content. Although SpO_2 readings may appear normal, an anemic patient may be hypoxic. Correcting anemia can improve arterial oxygen content. The pulse oximeter may fail to provide an SpO_2 if hemoglobin levels fall below 5 gm/dl.

Saturation

The N-560 will only measure saturation levels between 1 and 100%.

Pulse rates

The N-560 will only measure pulse rates between 20 and 250 beats per minute. Detected pulse rates outside the range of 20 to 250 beats per minute are displayed as the closest value within the range.

Sensor Performance Considerations

WARNING: Pulse oximetry readings and pulse signal can be affected by certain ambient conditions, sensor application errors, and certain patient conditions.

Inaccurate measurements can be caused by:

- incorrect application of the sensor
- placement of the sensor on an extremity with a blood pressure cuff, arterial catheter, or intravascular line
- ambient light
- excessive patient movement

Loss-of-pulse signal can occur for the following reasons:

- the sensor is applied too tightly

- a blood pressure cuff is inflated on the same extremity as the one with the sensor attached
- there is arterial occlusion proximal to the sensor

Use only Nellcor sensors and sensor cables.

WARNING: The use of accessories, sensors, and cables other than those specified may result in increased emission and/or decreased immunity and inaccurate readings of the N-560 pulse oximeter.

Select an appropriate sensor, apply it as directed, and observe all warnings and cautions presented in the directions for use accompanying the sensor. Clean and remove any substances such as nail polish from the application site. Periodically check to ensure that the sensor remains properly positioned on the patient.

WARNING: Tissue damage can be caused by incorrect application or inappropriate duration of use of an SpO_2 sensor. Inspect the sensor site as directed in the sensor directions for use.

High ambient light sources such as surgical lights (especially those with a xenon light source), bilirubin lamps, fluorescent lights, infrared heating lamps, and direct sunlight can interfere with the performance of an SpO_2 sensor. To prevent interference from ambient light, ensure that the sensor is properly applied and cover the sensor site with opaque material.

Caution: Failure to cover the sensor site with opaque material in high ambient light conditions may result in inaccurate measurements.

If patient movement presents a problem, try one or more of the following remedies to correct the problem.

- verify that the sensor is properly and securely applied
- move the sensor to a less active site
- use an adhesive *OxiMax* sensor that improves patient skin contact
- use a new sensor with fresh adhesive backing

- Keep the patient still, if possible

If poor perfusion affects performance, consider using the *OXIMAX* MAX-R sensor; it obtains measurements from the nasal septal anterior ethmoid artery, an artery supplied by the internal carotid artery. This sensor may obtain measurements when peripheral perfusion is relatively poor.

Operator's Menu

This operator's menu (Table 3) provides a quick reference to the functions on the N-560. The functions that are in **Bold** are the default settings.

Table 3: Operator's Menu

Menu	Sub-Menu	Function	Reference Paragraph
1	—	Trend print (tabular N-560 trend only)	*Trend Data Printout* on page 57
2	—	Trend clear	*Clearing Trend Information* on page 40
3	—	Language **English**	—
4	—	Baud rate:	*Setting the Data Port Baud Rate* on page 37
—	24	2400 baud	—
—	96	9600 baud	—
—	192	19200 baud	—
5	—	Data Port Protocol:	*Setting the Data Port Protocol* on page 39
—	1	**ASCII**	—
—	2	External equipment communications.	Refer to the external equipment manuals for the interfacing instructions.

Troubleshooting

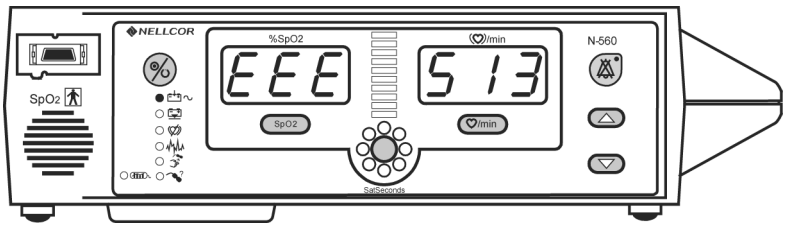
WARNING: If you are uncertain about the accuracy of any measurement, check the patient's vital signs by alternate means; then make sure the N-560 is functioning correctly.

WARNING: The cover should be removed only by qualified service personnel. There are no user-serviceable parts inside.

CAUTION: Do not spray, pour, or spill any liquid on the N-560, its accessories, connectors, switches, or openings in the chassis.

Error Codes

When the N-560 detects an error condition, it may display the letters "EEE" followed by an error code.



When an error code is displayed, turn the N-560 off, wait 10 seconds, and turn the N-560 on. If the error code is listed in Table 4, follow the action(s) listed. If the action does not correct the error condition, notify service personnel. If the error code is not listed in Table 4, notify service personnel.

When the N-560 detects a defective sensor connected to the N-560 the N-560 displays an error code of "Sen Err." The sensor should be replaced and the N-560 power should be recycled.

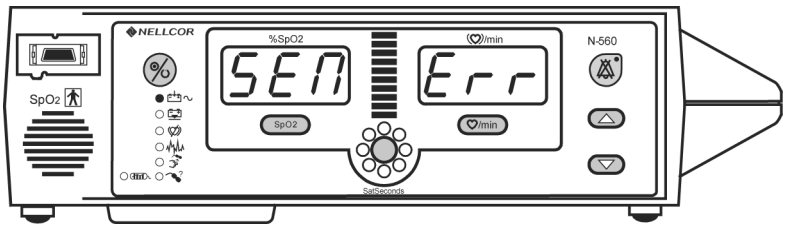


Table 4: Error Codes

Error Code	Action
513	1 — Charge the battery. 2 — Notify service personnel.
514	1 — Restart the N-560. 2 — Notify service personnel.
525	1 — Restart the N-560. 2 — Notify service personnel.
526	1 — Restart the N-560. 2 — Notify service personnel.
528	1 — Restart the N-560. 2 — Notify service personnel.

Corrective Action

If you experience a problem while using the N-560 and are unable to correct it, contact Nellcor's Technical Services Department or your local Nellcor representative. The N-560 service manual, which is for use by qualified service personnel, provides additional troubleshooting information.

Following is a list of possible problems and suggestions for correcting them.

1. **There is no response to the Power On/Off button.**

   - If the N-560 is operating on AC power, the fuse may be blown. Notify service personnel to check and, if necessary, replace the fuse.
   - If the N-560 is on battery power, the battery fuse may require replacement, the battery may be missing, or the battery may be discharged. Charge the battery or notify service personnel to replace the battery or the battery fuse, as required.

2. **One or more display segments or indicators do not light during the power-on self-test.**

   - Do not use the N-560; contact qualified service personnel or your local Nellcor representative.

3. **The N-560 does not sound a tone indicating successful completion of the Power-On Self-Test (POST).**

   - The N-560 has failed the power-on self-test. Do not use the N-560. This tone not only indicates the successful completion of POST, but it confirms that the audible alarm is functional. Contact qualified service personnel or your local Nellcor representative.

4. **The Pulse Search indicator is lit for more than 10 seconds while the sensor is connected to the patient.**

   - Check the sensor directions for use to determine if an appropriate sensor is being used and if it is applied properly. Check sensor and sensor cable connections. Test the sensor on someone else. Try another sensor or sensor cable.

- Perfusion may be too low for the N-560 to track the pulse. Check the patient. Test the N-560 on someone else. Change the sensor site. Try another type of sensor.
- Interference may be preventing the N-560 from tracking the pulse. Verify that the *OxiMax* sensor is securely applied and replace it if necessary. Change the *OxiMax* sensor site. Use a type of *OxiMax* sensor that maintains better contact with the patient's skin, such as an adhesive *OxiMax* sensor.
- Electromagnetic interference may be preventing the N-560 from tracking the pulse. Remove the source of interference (e.g., isolate the electromagnetic source or stabilize the sensor site). See the caution in the EMI (Electro-magnetic Interference) section on page 79.
- The sensor may be too tight, there may be excessive ambient light, or the sensor may be on an extremity with a blood pressure cuff, arterial catheter, or intravascular line. Reposition the sensor, as necessary.

5. The Pulse Search indicator lights after successful measurements have been made.

- Check the patient.
- Perfusion may be too low for the N-560 to track the pulse. Test the N-560 on someone else. Change the sensor site. Try another type of sensor. Refer to *Sensor Performance Considerations* on page 70.
- Interference may be preventing the N-560 from tracking the pulse. Verify that the *OxiMax* sensor is securely applied and replace it if necessary. Change the *OxiMax* sensor site. Use a type of *OxiMax* sensor that maintains better contact with the patient's skin, such as an adhesive *OxiMax* sensor.
- Electromagnetic interference may be preventing the N-560 from tracking the pulse. Remove the source of interference (e.g., isolate the electromagnetic source or stabilize the sensor site). See the caution in the EMI (Electro-magnetic Interference) section on page 79.

- The *OxiMax* sensor may be too tight, there may be excessive ambient light, or the *OxiMax* sensor may be on an extremity with a blood pressure cuff, arterial catheter, or intravascular line. Reposition the sensor, as necessary.

6. **The letters EEE, followed by a number, appear on the display.**

- This is an error code. To confirm, press the **Power On/Off** button to turn the N-560 off, then press the button again to turn it back on. If the display shows the error code once again, record the number and provide that information to qualified service personnel, or your local Nellcor representative.
- Error Code “EEE 513" is displayed when the battery is discharged to a critically low level. Turn the N-560 off and let it charge for about 10 minutes and then turn the N-560 back on. If the error code is still present, turn the N-560 off and let it continue to charge. If the N-560 has been charged for 30 minutes and the error code is still present, notify service personnel.

Refer to the N-560 service manual for a complete listing of error codes.

EMI (Electro-magnetic Interference)

CAUTION: This device has been tested and found to comply with the limits for medical devices to the IEC 60601-1-2, EN60601-1-2, and the Medical Device Directive 93/42/EEC. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation.

However, because of the proliferation of radio-frequency transmitting equipment and other sources of electrical noise in health care environments (for example, electrosurgical units, cellular phones, mobile two-way radios, electrical appliances, and high-definition television), it is possible that high levels of such interference due to close proximity or strength of a source may result in disruption of performance of this device.

The N-560 is designed for use in environments in which the pulse can be obscured by electromagnetic interference. During such interference, measurements may seem inappropriate or the N-560 may not seem to operate correctly.

Disruption may be evidenced by erratic readings, cessation of operation, or other incorrect functioning. If this occurs, the site of use should be surveyed to determine the source of this disruption, and the following actions taken to eliminate the source:

- Turn equipment in the vicinity off and on to isolate the offending equipment.
- Reorient or relocate the interfering equipment.
- Increase the separation between the interfering equipment and this equipment.

The N-560 generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with these instructions, may cause harmful interference with other devices in the vicinity.

If assistance is required, contact Nellcor's Technical Services Department, 1.800.635.5267, or your local Nellcor representative.

Obtaining Technical Assistance

For technical information and assistance, or to order parts or a service manual, contact Nellcor's Technical Services Department, 1.800.635.5267, or your local Nellcor representative. The service manual includes block diagrams and a parts list required by qualified personnel when servicing the N-560.

When calling Nellcor's Technical Services Department, 1.800.635.5267, or your local Nellcor representative, you may be asked to tell the representative the software version number of your N-560.

The device version appears in the N-560 display each time the N-560 successfully completes the power-on self-test. Write the number down and have it available whenever requesting technical assistance.

The most recent revision of this manual and the service manual are available on the Internet at:

http://www.mallinckrodt.com/respiratory/resp/Serv_Supp/ProductManuals.html

Maintenance

CAUTION: Follow local governing ordinances and recycling instructions regarding the disposal or recycling of device components and accessories.

Returning the N-560

Contact Nellcor's Technical Services Department, 1.800.635.5267, or your local Nellcor representative for shipping instructions including a Returned Goods Authorization (RGA) number. Unless otherwise instructed by Nellcor's Technical Services Department, it is not necessary to return the sensor or other accessory items with the N-560. Pack the N-560 in its original shipping carton. If the original carton is not available, use a suitable carton with appropriate packing material to protect it during shipping.

Return the N-560 by any shipping method that provides proof of delivery.

Service

WARNING: The cover should be removed only by qualified service personnel. There are no user-serviceable parts inside.

The N-560 requires no routine service or calibration other than changing the battery at least every 24 months. Refer to the N-560 service manual for the battery changing procedure.

If service is necessary, contact qualified service personnel or your local Nellcor representative.

Periodic Safety Checks

It is recommended that the following checks be performed every 24 months:

- Inspect the equipment for mechanical and functional damage.
- Inspect the safety-relevant labels for legibility.

Cleaning

CAUTION: Do not spray, pour, or spill any liquid on the N-560, its accessories, connectors, switches, or openings in the chassis.

For *surface cleaning* and *disinfecting* the N-560, follow your institution's procedures or:

- The N-560 may be *surface cleaned* by using a soft cloth dampened with either a commercial, nonabrasive cleaner or a solution of 70% alcohol in water, and lightly wiping the surfaces of the N-560.
- The N-560 may be *disinfected* using a soft cloth saturated with a solution of 10% chlorine bleach in tap water.

Before attempting to clean an SpO_2 sensor, read the directions for use enclosed with the sensor. Each sensor model has cleaning instructions specific to that sensor.

Technical Information

Description of Alarms

The N-560 has three levels of audible alarms.

1. *High-priority alarm*: A high-pitched, fast-pulsating tone indicating loss of pulse with no patient motion.

2. *Medium-priority alarm*: A medium-pitched, normal-pulsating tone indicating an SpO_2 or pulse rate limit violation.

   During a medium-priority alarm, the green display turns red and flashes with the patient parameter that violated the limit (%SpO_2 or Pulse Rate). If the alarm is a *SatSeconds* alarm, the *SatSeconds* indicator (clock) will flash.

3. *Low-priority alarm*: A low-pitched, slow-pulsating tone indicating a sensor disconnect, low battery, or N-560 failure.

   During a low-battery alarm, the **Low Battery** indicator illuminates and the alarm tone sounds immediately, even if the alarms are silenced or set to OFF.

Factory Defaults

The N-560 is shipped with factory default settings. Authorized technical personnel using the procedures described in the N-560 service manual can change default settings.

Table 5: Factory Default Settings

Parameter	Range	Factory Default Setting
%SpO2 Upper Alarm Limit	Lower Alarm Limit plus 1 to 100%	100%
%SpO2 Lower Alarm Limit	20% to Upper Alarm Limit minus 1	85%
Pulse Rate Upper Alarm Limit	Lower Alarm Limit plus 1 to 250 bpm	170 bpm
Pulse Rate Lower Alarm Limit	30 bpm to Upper Alarm Limit minus 1	40 bpm
Alarm Silence Reminder	On or Off	On
Alarm Silence Duration	Off, 30, 60, 90, 120 seconds	60 seconds
Alarm Silence Restrictions	• Audible reminder • No audible reminder • Do not allow alarms off	Audible reminder
Alarm Sound Selector	1, 2, 3	1
Alarm Volume	1 to 10	4
Data Port Baud Rate	2400, 9600, 19200	19200
Data Port Protocol	1, 2	1 (ASCII)
Display	0, 1	0 (On)
In-Sensor Trend Mode	0, 1, 2	0 (Event SpO2)
Language	English	English
Pulse Beep Volume	0 to 10	4
RS-232 Nurse Call Priority	Normally high, normally low	Normally low
SatSeconds	Off, 10, 25, 50, 100	Off

Table 5: Factory Default Settings (Cont.)

Parameter	Range	Factory Default Setting
Silence Alarms	0, 1	1 (Off)

SatSeconds Display

When the N-560 *SatSeconds* technology detects an SpO_2 value outside the alarm limit, the *SatSeconds* indicator LEDs begin to light (fill) clockwise. When the SpO_2 value is within the set limits, the *SatSeconds* indicator LEDs will extinguish counterclockwise.

When all of the *SatSeconds* indicator LEDs are lit, indicating that the *SatSeconds* setting has been reached, an audible alarm sounds and the *SatSeconds* indicator LEDs flash. As with traditional alarm management, the audible alarm may be silenced by pressing the **Alarm Silence** button.

Note: When a *SatSeconds* setting other than OFF is selected, the green LED at the top of the *SatSeconds* indicator will light. The green LED indicates that *SatSeconds* have been engaged.

Describing *SatSeconds*

With traditional alarm management, upper and lower alarm limits are set for monitoring oxygen saturation. During monitoring, as soon as an alarm limit is violated by as little as one percentage point, an audible alarm immediately sounds. When the $\%SpO_2$ level fluctuates near an alarm limit, the alarm sounds each time the limit is violated. Such frequent alarms can be distracting.

The N-560 utilizes Nellcor *SatSeconds* alarm management. With the *SatSeconds* technique, upper and lower alarm limits are set in the same way as traditional alarm management. However, the clinician also sets a *SatSeconds* limit that allows monitoring of $\%SpO_2$ below the selected lower alarm limit and above the selected upper alarm limit for a period of time before an audible alarm sounds.

The *SatSeconds* limit controls the time that the $\%SpO_2$ level may fall below the alarm limit before an audible alarm sounds.

The method of calculation is as follows:

The number of percentage points that the %SpO_2 falls outside the alarm limit is multiplied by the number of seconds that the %SpO_2 level remains outside that limit. This can be stated as an equation:

Points x Seconds = *SatSeconds*

Where:

Points = SpO_2 percentage points outside of the limit

Seconds = number of seconds that SpO_2 remains at that point outside of the limit

The alarm response time, assuming a *SatSeconds* limit set at 50 and a lower alarm limit set at 90, is described and illustrated below.

In this example, the %SpO_2 level drops to 88 (2 points) and remains there for a period of 2 seconds (2 points x 2 seconds = 4). The %SpO_2 then drops to 86 for 3 seconds and then to 84 for 6 seconds. The resulting *SatSeconds* are:

%SpO_2		Seconds		SatSeconds
2	x	2	=	4
4	x	3	=	12
6	x	6	=	36
Total Sat Seconds			=	52

After approximately 10.9 seconds, the *SatSeconds* alarm will sound, because 50 *SatSeconds* will have been exceeded. See arrow (↑) in Figure 6.

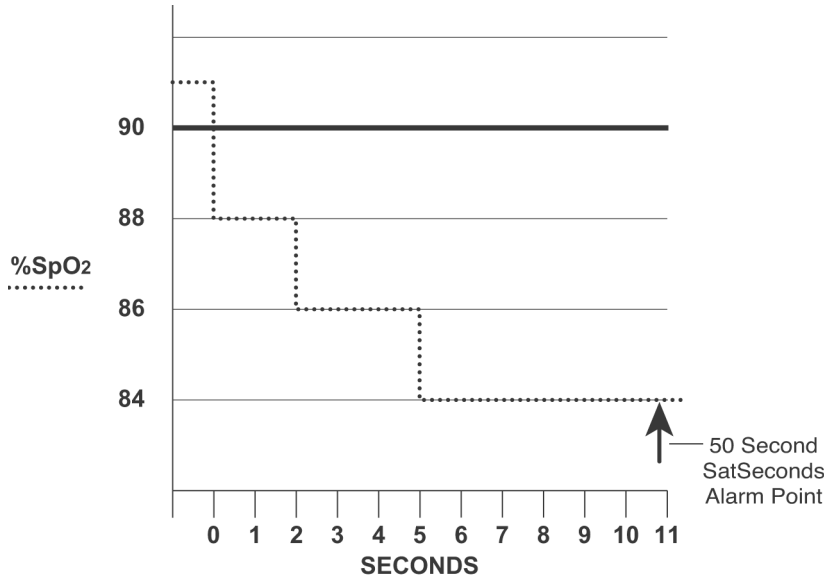


Figure 6: Alarm Response with *SatSeconds*

Saturation levels may fluctuate rather than remaining steady for a period of several seconds. Often, %SpO2 levels may fluctuate above and below the alarm limit, reentering the non-alarm range several times.

During such fluctuation, the N-560 integrates the number of %SpO2 points, both positive and negative, until either the *SatSeconds* limit (*SatSeconds* setting) is reached, or the %SpO2 level returns within a normal range and remains there.

SatSeconds "Safety Net"

The *SatSeconds* "Safety Net" is for patients whose saturation levels frequently go below the limit but do not stay below the limit long enough for the *SatSeconds* setting to be reached. When 3 or more limit violations occur in 60 seconds, an alarm will sound even if the *SatSeconds* setting has not been reached.

Principles of Operation

Oximetry Overview

The N-560 uses pulse oximetry to measure functional oxygen saturation in the blood. Pulse oximetry works by applying a sensor to a pulsating arteriolar vascular bed, such as a finger or toe. The sensor contains a dual light source and a photo detector.

Bone, tissue, pigmentation, and venous vessels normally absorb a constant amount of light over time. The arteriolar bed normally pulsates and absorbs variable amounts of light during the pulsations. The ratio of light absorbed is translated into a measurement of functional oxygen saturation (SpO_2).

Because a measurement of SpO_2 is dependent upon light from the sensor, excessive ambient light can interfere with this measurement.

Specific information about ambient conditions, sensor application, and patient conditions is contained throughout this manual.

Pulse oximetry is based on two principles: that oxyhemoglobin and deoxyhemoglobin differ in their absorption of red and infrared light (spectrophotometry), and that the volume of arterial blood in tissue (and hence, light absorption by that blood) changes during the pulse (plethysmography). A pulse oximeter determines SpO_2 by passing red and infrared light into an arteriolar bed and measuring changes in light absorption during the pulsatile cycle. Red and infrared low-voltage light-emitting diodes (LED) in the oximetry sensor serve as light sources; a photo diode serves as the photo detector.

Because oxyhemoglobin and deoxyhemoglobin differ in light absorption, the amount of red and infrared light absorbed by blood is related to hemoglobin oxygen saturation. To identify the oxygen saturation of arterial hemoglobin, the N-560 uses the pulsatile nature of arterial flow. During systole, a new pulse of arterial blood enters the vascular bed, and blood volume and light absorption increase. During diastole, blood volume and light absorption reach their lowest point. The N-560 bases its

SpO_2 measurements on the difference between maximum and minimum absorption (measurements at systole and diastole). By doing so, it focuses on light absorption by pulsatile arterial blood, eliminating the effects of nonpulsatile absorbers such as tissue, bone, and venous blood.

There are various matrixes within the *OxiMax* algorithm. Some are used to assess the severity of conditions presented to the N-560 in measuring SpO_2 and pulse rate. These individual matrixes or combinations of these matrixes are used to drive the LED indicators on the N-560 front panel.

During challenging measurement conditions, which could be caused by low perfusion, interference, external interference, like ambient light, or a combination of these, the *OxiMax* algorithm automatically extends the amount of data required for measuring SpO_2 and pulse rate, depending on the measurement conditions. During normal measurement conditions in the Normal response mode, the averaging time is 6 to 7 seconds. If the resulting dynamic averaging time exceeds 20 seconds, the **Pulse Search** indicator is continuously illuminated and SpO_2 and pulse rate is updated every second. As measurement conditions become even more challenging, the amount of data required continues to extend. If the dynamic averaging time reaches 40 seconds, the **Pulse Search** indicator begins flashing and the SpO_2 and pulse rate display flashes zeros indicating a loss-of-pulse condition.

Automatic Calibration

Because light absorption by hemoglobin is wavelength dependent and because the mean wavelength of LEDs varies, an oximeter must know the mean wavelength of the sensor's red LED to accurately measure SpO_2.

During monitoring, the N-560's software selects coefficients that are appropriate for the wavelength of that individual sensor's red LED; these coefficients are then used to determine SpO_2.

Additionally, to compensate for differences in tissue thickness, the light intensity of the sensor's LEDs is adjusted automatically.

Functional versus Fractional Saturation

This N-560 measures functional saturation -- oxygenated hemoglobin expressed as a percentage of the hemoglobin that can transport oxygen. It does not detect significant amounts of dysfunctional hemoglobin, such as carboxyhemoglobin or methemoglobin. In contrast, hemoximeters such as the IL482 report fractional saturation -- oxygenated hemoglobin expressed as a percentage of all measured hemoglobin, including measured dysfunctional hemoglobins. To compare functional saturation measurements to those from an instrument that measures fractional saturation, fractional measurements must be converted as follows:

$$\text{functional saturation} = \frac{\text{fractional saturation}}{100 - (\%\,\text{carboxyhemoglobin} + \%\,\text{methemoglobin})} \times 100$$

Measured versus Calculated Saturation

When saturation is calculated from a blood gas partial pressure of oxygen (PO2), the calculated value may differ from the SpO_2 measurement of a pulse oximeter. This usually occurs because the calculated saturation was not appropriately corrected for the effects of variables that shift the relationship between PO2 and pH, temperature, the partial pressure of carbon dioxide (PCO2), 2,3-DPG, and fetal hemoglobin. See Figure 7.

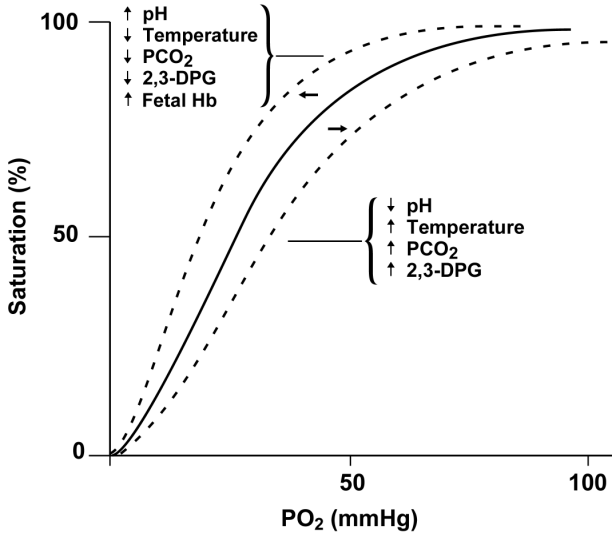


Figure 7: Oxyhemoglobin Dissociation Curve

Functional Testers and Patient Simulators

Some models of commercially available bench top functional testers and patient simulators can be used to verify the proper functionality of Nellcor pulse oximeter sensors, cables and monitors. See the individual testing device's operator's manual for the procedures specific to the model of tester being used.

While such devices may be useful for verifying that the pulse oximeter sensor, cabling, and monitor are performing as designed, they are incapable of providing the data required to properly evaluate the accuracy of a system's SpO_2 measurements. Fully evaluating the accuracy of the SpO_2 measurements requires, at a minimum, accommodating the wavelength characteristics of the sensor and reproducing the complex optical interaction of the sensor and the patient's tissue. These capabilities are beyond the scope of known bench top testers. SpO_2 measurement accuracy can only be evaluated in vivo by comparing pulse oximeter readings with values traceable to SaO_2 measurements obtained from simultaneously sampled arterial blood made using a laboratory CO-oximeter.

Many functional testers and patient simulators have been designed to interface with the pulse oximeter's expected calibration curves and may be suitable for use with Nellcor monitors and/or sensors. Not all such devices, however, are adapted for use with the Nellcor *OxiMax* digital calibration system. While this will not affect use of the simulator for verifying system functionality, displayed SpO_2 measurement values may differ from the setting of the test device. For a properly functioning monitor, this difference will be reproducible over time and from monitor to monitor within the performance specifications of the test device.

Specifications

Performance

Measurement Range

SpO_2	1% to 100%
Pulse Rate	0 and 20 beats per minute (bpm) to 250 bpm
Perfusion Range	0.03% to 20%

Accuracy and Interference Tolerance

Saturation	
Adults[1]	70 to 100% ±2 digits
Neonate	70 to 100% ±3 digits
Low Perfusion[2]	70 to 100% ±2 digits
Pulse Rate	
Adult and Neonate[1]	20 to 250 bpm ±3 digits
Low Perfusion[2]	20 to 250 bpm ±3 digits

[1] Adult specifications are shown for OXIMAX MAX-A and MAX-N sensors with the N-560. Neonate specifications are shown for OXIMAX MAX-N sensors with the N-560. Saturation accuracy will vary by sensor type. Refer to the Sensor Accuracy Grid. The Sensory Accuracy Grid is available on the Internet at:

http://www.mallinckrodt.com/respiratory/resp/Serv_Supp/Product-Manuals.html

[2] Specification applies to N-560 performance. Reading accuracy in the presence of low perfusion (detected IR pulse modulation amplitude <1.5%) was validated using signals supplied by a patient simulator. SpO_2 and pulse rate values were varied across the monitoring range including weak signal conditions and compared to the known true saturation and pulse rate of the input signals.

Table 6: Tone Definition

Audible Indicator	Parameter	Value
Alarm Silence Reminder	Volume level	Not changeable
	Pitch (±30 Hz)	784 Hz
	Pulse width (±20 ms)	150 ms
	Pulse repetition interval (±20 ms) (double burst)	150 ms
	Repetitions	3
Confirmation of Button Pressed	Volume level	Not changeable
	Pitch (±30 Hz)	784 Hz
	Pulse width (±20 ms)	150 ms
	Pulse repetition interval (±20 ms) (double burst)	150 ms
	Repetitions	3
High Priority Alarm	Volume level	Adjustable alarm volume
	Pitch (±30 Hz)	932 Hz
	Pulse width (±20 ms)	Nellcor = 255 ms
		IAW IEC 60601-1-8 = 120 ms
		IAW EN 475 = 150 ms
	Pulse repetition interval (±20 ms) (double burst)	Nellcor = 320 ms
		IAW IEC 60601-1-8 = 6940 ms
		IAW EN 475 = 7500 ms
	Repetitions	Continually

Table 6: Tone Definition (Cont.)

Audible Indicator	Parameter	Value
Invalid Button Press	Volume level	Not changeable
	Pitch (±30 Hz)	180 Hz
	Pulse width (±20 ms)	70 ms
	Pulse repetition interval (±20 ms) (double burst)	N/A
	Repetitions	1
Low Priority Alarm	Volume level	Adjustable alarm volume
	Pitch (±30 Hz)	500 Hz
	Pulse width (±20 ms)	200 ms
	Pulse repetition interval (±20 ms) (double burst)	15000 ms
	Repetitions	Continually
Medium Priority Alarm	Volume level	Adjustable alarm volume
	Pitch (±30 Hz)	752 Hz
	Pulse width (±20 ms)	Nellcor = N/A
		IAW IEC 60601-1-8 = 160 ms
		IAW EN 475 = 200 ms
	Pulse repetition interval (±20 ms) (double burst)	Nellcor = N/A
		IAW IEC 60601-1-8 = 7600 ms
		IAW EN 475 = 20000 ms
	Repetitions	Continually

Table 6: Tone Definition (Cont.)

Audible Indicator	Parameter	Value
POST Pass	Volume level	Not changeable
	Pitch (±30 Hz)	784 Hz
	Pulse width (±20 ms)	1000 ms
	Pulse repetition interval (±20 ms) (double burst)	N/A
	Repetitions	1
Pulse Beep	Volume level	Adjustable
	Pitch (±30 Hz)	296 Hz to 662 Hz (varies with saturation)
	Pulse width (±20 ms)	40 ms
	Pulse repetition interval (ms ±20 ms) (double burst)	N/A
	Repetitions	1
Valid Button Press	Volume level	Not changeable
	Pitch (±30 Hz)	784 Hz
	Pulse width (±20 ms)	30 ms
	Pulse repetition interval (±20 ms) (double burst)	N/A
	Repetitions	1
Volume Setting	Volume level	Adjustable alarm volume
	Pitch (±30 Hz)	752 Hz
	Pulse width (±20 ms)	Infinite
	Pulse repetition interval (±20 ms) (double burst)	N/A
	Repetitions	N/A

Electrical

Instrument

Power Requirements	100 to 240 volts AC, 25 to 39 volt/amps to be compliant with IEC 60601-1 sub-clause 10.2.2
Fuses	qty 2, 2 A, 250 volts, slow-blow, IEC (5 x 20 mm)

Battery

The battery provides at least eight hours of battery life when new and fully charged with no alarms, no serial data, while using a pulse simulator set for 60 bpm, high light and low modulation.	
Type	Nickel metal hydride
Voltage	9.6 volts DC, 3.8 AH
Recharge	6 hours
Shelf Life	3 months, new, fully charged battery After 3 months storage the N-560 will run for 50% of stated battery life
Complies With	91/157/EEC

Sensors

Electrical/Optical Specifications	Nellcor Pulse oximetry sensors contain light emitting diodes (LEDs) that emit red (~660 nm) and infrared (~900 nm) light, with a total optical output power of less than 15 mW. This information of sensor wavelength range can be especially useful to clinicians, for example, those performing photodynamic therapy.

Environmental Conditions

Operation

Temperature	50 ºF to 113 ºF (10 ºC to 45 ºC)
Altitude/Barometric Pressure	-390 m to 3,012 m (-1,280 ft. to 9,882 ft.) 70 kPa to 106 kPa (20.6 in. Hg to 31.3 in. Hg)
Relative Humidity	15% to 95% non-condensing to be compliant with IEC 60601-1, sub-clause 44.5

Transport and Storage (not in shipping container)

Temperature	-4 ºF to 140 ºF (-20 ºC to 60 ºC)
Altitude/Barometric Pressure	-390 m to 5,574 m (-1,280 ft. to 18,288 ft.) 50 kPa to 106 kPa (14 in. Hg to 31.3 in. Hg)
Relative Humidity	15% to 95% non-condensing over temperature range of -4 ºF to 140 ºF (-20 ºC to 60 ºC)

Transport and Storage (in shipping container)

Temperature	-4 ºF to 158 ºF (-20 ºC to 70 ºC)
Altitude/Barometric Pressure	-390 m to 5,574 m (-1,280 ft. to 18,288 ft.) 50 kPa to 106 kPa (14 in. Hg to 31.3 in. Hg)
Relative Humidity	15% to 95% non-condensing

Sensor Power Dissipation

Sensor	Dissipation
OxiMax MAX-N	52.5 mW
OxiMax MAX-I	52.5 mW

Sensor Power Dissipation (Cont.)

Sensor	Dissipation
OxiMax MAX-P	52.5 mW
OxiMax MAX-A	52.5 mW
OxiMax MAX-AL	52.5 mW
OxiMax MAX-R	52.5 mW
OxiMax Oxiband OXI-A/N	52.5 mW
OxiMax Oxiband OXI-P/I	52.5 mW
OxiMax Durasensor DS-100A	52.5 mW
OxiMax OxiCliq P	52.5 mW
OxiMax OxiCliq N	52.5 mW
OxiMax OxiCliq I	52.5 mW
OxiMax OxiCliq A	52.5 mW
OxiMax Dura-Y D-YS	52.5 mW
OxiMax MAX-FAST	52.5 mW
OxiMax Softcare SC-PR	52.5 mW
OxiMax Softcare SC-NEO	52.5 mW
OxiMax Softcare SC-A	52.5 mW

Physical Characteristics

Weight	3.07 lbs. (1.39 kg) without pole mount
Dimensions	2.95 " (H) × 9.06 " (W) × 5.04" (D) 75 mm (H) × 230 mm (W) × 128 mm (D)

Compliance

Item	Standard	Description
Quality System	EN ISO 13485: 2000, ISO 13485: 1996	Quality system — Medical Devices, Particular Requirements for application of ISO 9001: 2000
EC Directive	93/42/EEC	Medical Device Directive (Europe + Int.)
FDA Guidance	FDA RG (Nov. 1993)	Reviewers Guide for Premarket Notification Submission
Safety — EC	EN 60601-1: 1995	General Rqmts for Safety, Medical Equipment
Safety — USA	UL 60601-1: 2003	Safety — Medical Electrical System
Safety — Canada	CSA C22.2 No 601, 1-M90: 1998	Safety — Medical Electrical Sys, Requires NRTL Listing
Electric Shock Classification	EN 60601-1	Class I or Internally powered (Battery mode), Type BF Applied part
Protection against Water Classification	EN 60601-1	IPX1
Mode of Operation Classification	EN 60601-1	Continuous Operation
Flammable Anaesthetic Classification	EN 60601-1	Equipment not suitable
Safety	ISO 9919: 2005(E)	Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use.
EMC	EN 60601-1-2	Medical Electric Equipment, Collateral Standard: EMC-Requirements and Test, 2nd Edition, 2001

Item	Standard	Description
EMC	EN 55011, Class B/ Group 1	EMC Disturbance Characteristics — Limits and Methods of Measurement, Industrial Scientific and Medical (ISM) RF Equipment, Edition 3.1,1999-08
Safety Alarms	EN 60601-1-8: 2004	General Application of Alarms in Medical Electric Equipment
Front panel and case labeling	IEC 60878, EN 980, ISO 7000, EN 60417-1, EN 60417-2	
Button spacing	ISO 7250	
Year of manufacture symbol	EN 980	
Operation during physical shock	IEC 60068-2-27	
Operation during vibration	IEC 60068-2-6, IEC 60068-2-34	

Manufacturer's Declaration

This product complies with EN/IEC 60601-1-2:2001.

WARNING: The use of accessories, sensors, and cables other than those specified may result in increased emission and/or create invalid readings of the N-560.

Table 7: Cable Compliance

Cables Comply With:	
• RF emissions, EN 55011, Class B/Group 1 • EN 60601-1-2; 2001	
Cables and *OxiMax* Sensors	**Maximum Length**
OxiCliq-OC-3 cable	3 ft. (0.9 m)
DOC-10 pulse oximeter cable	10 ft. 10 in. (3.3 m)
Software download cable, RS-232 serial, 15 to 9 pin “D”	10 ft. (3 m)
Non-terminated cable, RS-232/Analog, 15 pin “D”	3.3 ft. (1 m)
Oxinet hardwire cable	10 ft. (3 m)
Printer cable, RS-232, 15 to 9 pin “D”	10 ft. (3 m)
Oxinet II data cable	10 ft. (3 m)
HP Agilent interface cable	3 ft. (0.9 m)
GE Marquette interface cable	3 ft. (0.9 m)
Datex-Ohmeda interface cable	3 ft. (0.9 m)
MAX-FAST sensor	30 in. (76.2 cm)
MAX-A sensor	1.5 ft. (0.5 m)
MAX-AL sensor	3 ft. (0.9 m)
MAX-I sensor	1.5 ft. (0.5 m)
MAX-N sensor	1.5 ft. (0.5 m)
MAX-P sensor	1.5 ft. (0.5 m)
MAX-R sensor	1.5 ft. (0.5 m)
SC-PR sensor	3 ft. (0.9 m)
SC-NEO sensor	3 ft. (0.9 m)
SC-A sensor	3 ft. (0.9 m)
DS-100A sensor	3 ft. (0.9 m)
OXI-A/N sensor	3 ft. (0.9 m)
OXI-P/I sensor	3 ft. (0.9 m)

Table 7: Cable Compliance (Cont.)

Cables Comply With: (Cont.)	
• RF emissions, EN 55011, Class B/Group 1 • EN 60601-1-2; 2001	
Cables and *OxiMax* Sensors (Cont.)	**Maximum Length**
D-YS sensor	4 ft. (1.2 m)
D-YSE sensor	4 ft. (1.2 m)
D-YSPD sensor	4 ft. (1.2 m)

Table 8: Electromagnetic Emissions

The N-560 is intended for use in the electromagnetic environment specified below. The customer or the user of the N-560 should assure that it is used in such an environment.

Emission Test	Compliance	Electromagnetic Environment — Guidance
RF emissions CISPR 11	Group 1	The N-560 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The N-560 is suitable for use in establishments, including diagnostic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic Emissions IEC 61000-3-2	Class D	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

Table 9: Electromagnetic Immunity

The N-560 is intended for use in the electromagnetic environment specified below. The customer or user of the N-560 should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment — Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	Complies	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV power supply lines ±1 kV for input/output lines	Complies	Mains power should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	Complies	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (95% dip in U_T) for 0.5 cycle	Complies	Mains power quality should be that of a typical commercial or hospital environment. If the user of the N-560 requires continued operation during power mains interruptions, it is recommended that the N-560 be powered from an uninterruptible power supply or battery.
	40% U_T (60% dip in U_T) for 5 cycles	Complies	
	70% U_T (30% dip in U_T) for 25 cycles	Complies	
	<5% U_T (>95% dip in U_T) for 5 seconds	Complies	

Table 9: Electromagnetic Immunity (Cont.)

The N-560 is intended for use in the electromagnetic environment specified below. The customer or user of the N-560 should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment — Guidance
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	Complies	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: U_T is the AC mains voltage prior to application of the test level.			
Conducted RF IEC 61000-4-6	3 Vrms 150 kHZ to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the N-560, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	

Table 9: Electromagnetic Immunity (Cont.)

The N-560 is intended for use in the electromagnetic environment specified below. The customer or user of the N-560 should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment — Guidance
Recommended separation distance: $d = [\frac{3.5}{V_1}]\sqrt{P}$ 150 kHz to 80 MHz $d = [\frac{3.5}{E_1}]\sqrt{P}$ 80 MHz to 800 MHz $d = [\frac{3.5}{E_1}]\sqrt{P}$ 800 MHz to 2.5 GHz [b] Interference may occur in the vicinity of equipment marked with this symbol:			where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, [a] should be less than the compliance level in each frequency range.

Note 1: At 80 MHz, the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] Field strength from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in which the N-560 is used exceeds the applicable RF compliance level above, the N-560 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the N-560.

[b] Over the frequency range 150 kHz to 80 MHz, field strength should be less than 3 V/m.

Table 10: Recommended Separation Distances Between Portable and Mobile RF Communication Equipment and the N-560

The N-560 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the N-560 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the N-560 as recommended below, according to the maximum output power of the communications equipment.

Rated Maximum Output Power of the Transmitter W	Separation Distance according to Frequency of Transmitter m		
	150 kHz to 80 MHz $d = [\frac{3.5}{V_1}]\sqrt{P}$	80 MHz to 800 MHz $d = [\frac{3.5}{E_1}]\sqrt{P}$	800 MHz to 2.5 GHz $d = [\frac{7}{E_1}]\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note 1: At 80 MHz to 800 MHz, the separation distance for the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

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NELLCOR

Tyco Healthcare Group LP
Nellcor Puritan Bennett Division
4280 Hacienda Drive
Pleasanton, CA 94588 U.S.A.
Telephone Toll Free 1.800.NELLCOR

Authorized Representative
Tyco Healthcare UK LTD
154 Fareham Road
Gosport PO13 0AS, U.K.

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